Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

29 March 2016

Email: Codex.Contact@agriculture.gov.au
Janine.Lewis@foodstandards.gov.au

Dear Janine

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on the first consultation for 2016 from the CCNSFDU eWG on Follow-up Formula.

This is attached. You will note that in one area, we have not concluded our position (in relation to lactic acid) and will provide this to you tomorrow.

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported in Australia and New Zealand.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

Yours sincerely

Jan Carey
Chief Executive

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
Submitters Response Form

March 2016

Note: INC has inserted an additional and new section for IRON and VITAMIN A based on new data collected and collated by ISDI concerning Technical Feasibility. New Zealand and Australia contributed to this material and consider these areas should be reopened on the basis of Technical Feasibility.

Comments on Proposed Draft Revised Standard for Follow-up formula Part I at Step 4

VITAMIN A

Summary:

Although 37th session of CCNFSDU accepted a minimum and maximum for vitamin A, new data submitted by ISDI and contributed to by INC members indicates that a modified nutrient range for vitamin A should be considered and discussed.

While this is not an attractive option for the Committee, it will have a serious impact on manufacturing if it is not addressed at this time of review.

A broader nutrient range for vitamin A is recommended because of the serious constraints that the range agreed at the 37th session of CCNSFDU places on manufacturers. The technological feasibility has been reviewed and INC concurs with ISDI in requesting that the 38th session of CCNFSDU consider REDUCING the maximum level from 225 to 200 µg RE/100 kcal and REDUCING the minimum level from 75 to 60 µg RE/100 kcal. This provides a slightly wider range for manufacturing purposes.

Rationale - Scientific substantiation:

At the 37th session of CCNFSDU agreement was reached on the following minimum and maximum values for vitamin A:

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)]/100 kcal	75	180	-
µg RE[10)]/100 kJ	18	43	-

[10)] expressed as retinol equivalents (RE)

ISDI had submitted comments CRD11[1], considering that, based on preliminary data on technological feasibility, this range was too narrow.

Based on the final report on technological feasibility submitted to the chair of the eWG in February 2016 [2], ISDI has reiterated its concerns regarding the range being too narrow to manage vitamin A levels as part of its comments[3]. INC strongly agrees.

While in the previous ISDI comments it was requested that consideration be given to maintaining the minimum and maximum levels defined in the current Codex Standard for Follow-Up Formula (75 and 225 µg RE/100 kcal), INC and ISDI can accept in the light of the data submitted in the final report as well as in the spirit of compromise, that the maximum level should be reduced from 225 to 200 µg RE/100 kcal, and the minimum level reduced from 75 to 60 µg RE/100 kcal.

Both proposals are supported by the data provided in the ISDI Technical Feasibility Report. These changes enable management of:

- the nutritional requirements for vitamin A and

- concerns related to high intake of vitamin A
- technological challenges related to vitamin A supplementation of follow-up formula for older infants.

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)]/100 kcal	60	200	-
µg RE[10)]/100 kJ	14	48	-

[10)] expressed as retinol equivalents (RE)

References:

1. ISDI - CRD 11 (2015) Review of the standard for follow-up formula (Codex STAN 156-1987) – Comments of ISDI.
2. 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.
3. ISDI comments to 37th session of the CCNFSDU (2015) Review of the standard for follow-up formula (Codex STAN 156-1987). CX/NFSDU 15/37/5-Add.1

IRON

Summary:

Although the 37th session of CCNFSDU accepted a minimum and maximum for iron, new data submitted by ISDI indicates consideration should be given to a modified maximum level for iron. INC strongly supports this position.

INC supports the ISDI recommendation to adopt a higher maximum level for iron. ISDI has previously advocated setting the maximum at 2.5 mg/100 kcal. In view of the final ISDI Technological Feasibility Report, INC believes CCNSFDU should consider increasing the maximum iron level from 2.0 to 2.5 mg/100 kcal.

Rationale - Scientific substantiation:

At the 37th session of CCNFSDU agreement was reached on the following minimum and maximum values for iron.

Iron[17)]

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	1.0	2.0	-
mg /100 kJ	0.24	0.48	-

[17)] For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36mg/100 kJ) a maximum of 2.5 mg/100 kcal (0.6/100 kJ) applies.

ISDI had submitted comments on the proposed maximum iron level to the 37th session of CCNFSDU through CRD11 (1) based on preliminary data on technological feasibility that the proposed maximum was too low.

Based on ISDI's final Technological Feasibility Report submitted to the chair of the eWG in February 2016 (2), ISDI reiterated its concerns regarding the proposed maximum level for iron being too low. ISDI's rationale for increasing the maximum level is supported by data on the apparent history of safe use, the nutritional requirements for iron and technological challenges related to iron supplementation of follow-up formula for older infants.

INC highlights in this response the data collected from the ISDI survey of follow-up formula products and presented as part of the final ISDI Technological Feasibility Report of follow-up formula for older infants (2) demonstrating that many follow-up formulas for older infants routinely have iron levels above 2.0 mg/100kcal.

Iron supplemented formulas in the US have label declarations between 1.5 and 1.8 mg/100 kcal in order to meet a minimum iron level of 1.5 mg/100 kcal. This is due to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), resulting in actual iron levels being higher than the maximum value proposed by the 37th session of CCNFSDU of 2.0 mg/100 kcal.

The US Infant Formula Act defines the maximum iron level for infant formulas (0-12 months of age) at 3.0 mg/100 kcal. Historical data reveals that follow-up formulas for older infants (6-12 months) with actual levels at or above 2.0 mg/100 kcal represent approximately 80% of all formulas sold in the US for the past 5-10 years (in the US infant formulas cover 0-12 months of age and as such they are representative of follow-up formulas for older infants). An average of 4 million babies are born each year in the US, at least 3 million of whom are fed iron-fortified formulas. Identical formulas with the same iron levels have been available for many years in many other countries around the world as well (e.g. Latin America).

The revised iron requirements proposed are therefore as follows:

Iron[17)]

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	1.0	2.5	-
mg /100 kJ	0.24	0.60	-

[17)] For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36mg/100 kJ) applies.

Please note that footnote 17, as it currently stands, states a maximum of 2.5mg/100kcal (0.60mg/100kJ). This is the same as the new maximum proposed for milk-based formulas so it is proposed that the relevant text could then be omitted from the footnote as stated above.

In conclusion, follow-up formulas for older infants with iron levels up to 2.5 mg/100 kcal have a long history of apparent safe use as documented in the final ISDI Technological Feasibility Report of follow-up formula for older infants. Therefore, based on the totality of the available data, INC and ISDI propose a maximum of 2.5 mg/100 kcal, which is scientifically and technologically substantiated and enables accommodation of all the principles defined by Codex Alimentarius.

References:

1. 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.
2. ISDI - CRD 11 (2015) Review of the standard for follow-up formula (Codex STAN 156-1987) – Comments of ISDI.
3. ISDI comments to 37th session of the CCNFSDU (2015) Review of the standard for follow-up formula (Codex STAN 156-1987). CX/NFSDU 15/37/5-Add.1

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

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	

Summary:

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.

Based on the totality of data, and in particular new data, and while recognising the debate within the scientific and regulatory community regarding the adequate lower protein level for follow-up formula for older infants is ongoing, INC concurs with ISDI's recommendation that a lower minimum protein level at 1.65 g/100 kcal be adopted.

As substantiated in the next section, a footnote should accompany the protein level, to ensure that low protein levels are scientifically substantiated, and, when needed, clinically evaluated.

Rationale - Scientific justification:

A WHO/FAO/UNU review of protein requirements calculated protein requirements based on the factorial method which takes into consideration protein required for maintenance and growth (WHO/FAO/UNU 2007). The calculations were based on maintenance of requirements of 0.66 g/kg bodyweight per day and a protein efficiency utilisation of 58%. In the recently published opinion by EFSA regarding nutrient requirements and dietary intakes for infants and young children in the European Union, a similar approach was used (EFSA, 2013).

Recent estimates of protein requirements are lower as compared to previous ones primarily as a result of changes in the reference body weights previously used. Almost all recently derived values are based on the WHO/FAO/UNU report requirements per kg bodyweight (CX/NFSDU 14/36/7, 2014). Protein requirements for 6-12 month older infants calculated from WHO/FAO/UNU protein requirements (WHO/FAO/UNU 2007) using WHO weight-for-age growth standards (WHO 2006) result in 10.2 g/kg bodyweight.

For the minimum protein level of follow-up formula for older infants, ISDI refers to the proposal by the Early Nutrition Academy (ENA), which recently developed compositional recommendations for follow-up formula (Koletzko, 2013). Population reference intakes (PRI) for the dietary protein intake to meet the needs of basically all infants in the population with adequate safety margin was considered at 1.31 g protein/kg body weight at 6 months and at 1.14 g protein/kg body weight at 12 months (WHO, 2007; EFSA, 2012).

Using a daily energy intake of 80 kcal/kg bodyweight, this translated into a protein density for follow-up formula for older infants of 1.64 g/100 kcal and 1.43 g/100 kcal, using a PRI of 1.31 and of 1.14 g protein /kg at 6 months and 12 months, respectively (Koletzko, 2013). Therefore, ENA (Koletzko, 2013) recommends setting the minimum protein level of cows' milk-based follow-up formula for older infants at 1.65 g/100 kcal, taking into consideration good protein quality with an adequate content of bioavailable essential amino acids.

In addition to establishing nutritionally safe and adequate minimum protein levels for follow-up formula for older infants, several national and regional surveys of dietary protein intakes of older infants and young children are taken into consideration.

The results of these dietary surveys have consistently identified that average protein intakes in this age group are adequate for the majority of infants and young children (Agostoni 2006). A recent study conducted in France showed that infants and young children have protein intakes above recommended dietary requirements (SFAE, 2014). Similarly, surveys conducted in infants in selected Asian countries indicated average protein intakes ranged from 14 to 50 g/day (Poh, 2013; FNRI, 2008; Nguyen, 2013; Rojroongwasinkul, 2013).

Finally, ISDI has considered that the safety of use and the nutritional suitability of a formula with a protein content of 1.65 g/100 kcal has been established in infants. Two recent randomised clinical trials demonstrated adequate growth and development. Ziegler et al. (2015a,b) reported that infants receiving a follow-up formula for older infants with protein content of 1.61 g/100 kcal from age 3 to 12 months demonstrated similar growth to the control group receiving a formula with 2.15 g protein/100 kcal (Ziegler 2015). Similarly, Inostroza et al. (2014) demonstrated that infants born to overweight mothers have similar and adequate growth when receiving either a formula with 1.65 g protein/100 kcal or a control formula with 2.7 g protein/100 kcal from age 3 to 12 months.

In order to confirm their safety and suitability, INC and ISDI recommends that formulas with a low protein level should be scientifically substantiated, and when appropriate, clinically evaluated prior to placing on the market. Therefore a footnote should accompany the protein level.

In conclusion, based on the available data, and in particular the data from clinical trials published in the past two years, **INC concurs with the ISDI recommendation that a lower minimum protein level at 1.65 g/100 kcal be adopted similar to the requested level at the 37th session of CCNFSDU. However, in order to ensure lower protein levels are sufficiently substantiated, INC supports the introduction of a footnote requesting substantiation (see below).**

References:

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SFAE (2014) Résultats du 2e volet de l'Étude NutriBébé SFAE 2013 – Apports nutritionnels chez les 0 à 3 ans. *Journal de Pédiatrie et de Puériculture*, 27(5):265-269.

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WHO Child Growth Standards (2006) http://www.who.int/childgrowth/standards/weight_for_age/en/

WHO (2005) Guiding Principles for feeding of non-breastfed children 6-24 months of age. World Health Organization: Geneva.

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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

Summary:

INC supports the ISDI position for a maximum protein level of 3.5 g/100 kcal. As 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.

INC recommends adoption of a maximum protein level of 3.5 g/100 kcal in the revised Codex Standard for Follow-Up Formula for older infants (Codex STAN 156-1989).

Rationale - Scientific justification:

Establishing a standard requires considerations about meeting nutritional requirements as well as managing upper safe and suitable nutrient intake levels. Given the global perspective of Codex Alimentarius, the assessments of both minimum and maximum levels become a challenging exercise for most nutrients. Both minimum and maximum safe and suitable nutritional requirements require tailoring to each geographical, national or dietary setting which, from a global perspective that is less than uniform. As a consequence setting minimum and maximum levels, particularly for protein, is challenging.

INC supported a maximum protein level of 3.5 g/100 kcal, that was substantiated. INC supports the ISDI reiteration of the scientific and international trade related aspects below:

1. Scientific substantiation:

   Establishing the upper protein level requires assessment of the totality of scientific evidence regarding safety and suitability of the maximum proposed protein level. As a result, the focus is on scientific expert opinions regarding upper safe protein intake levels. Neither EFSA (2014) nor WHO/FAO (2007) establish an upper limit for protein for older infants.

   The maximum proposed protein limit of 3.5 g protein/100 kcal is safe and suitable for consumption by older infants, has a long history of apparent safe use and has been globally marketed since the origin of the Codex Standard for Follow-up Formula (Codex STAN 156-1987).

   The following considerations have been taken into account in establishing the above recommendation:
   - Maximum protein values proposed for follow-up formula for older infants are extrapolated from minimum protein requirements, rather than from specific clinical data in older infants supporting safety and suitability of the upper protein levels.
   - Protein requirements for infants and young children (WHO/FAO, 2007) are defined as the minimum intake that will allow nitrogen equilibrium at an appropriate body composition during energy balance at moderate physical activity, plus the needs associated with the deposition of tissues consistent with good health.

- WHO/FAO (2007) highlights that the definition of protein requirement based upon nitrogen balance does not identify the optimal level of protein for long term health:
  "*It is acknowledged that this definition of the requirement in terms of nitrogen balance does not necessarily identify the optimal intake for health, which is less quantifiable*".
- WHO/FAO (2007) also emphasises that:
  "*Current knowledge of the relationship between protein intake and health is insufficient to enable clear recommendations about either optimal intakes for long-term health or to define a safe upper limit*".
- A maximum protein level of 3.5 g/100 kcal would provide 14% of total energy from protein, which is aligned with European and North American data. European data indicates that the range of protein typically consumed by 6-12 month old infants varies between 10-15% of total energy (Lagström, 1997; Noble, 2001; Hilbig, 2005; de Boer, 2006; DGE, 2008; Fantino, 2008; Marriott, 2008; Lennox, 2013; EFSA, 2014). Similarly, US data (Butte, 2010) reports that protein intake as a percentage of energy increased with age and were within the recommendations by the Institute of Medicine (2002) for acceptable macronutrient distribution range (AMDR) of 5-20% of energy.
- Consideration should be given to the diversity of protein intakes across the globe in establishing the maximum protein level, which should enable both protein intake of older infants living in resource-rich and resource-limited settings. As reported in CX/NFSDU 14/36/7 2014 :
  It is acknowledged that some sub-groups of the population will be at risk of protein deficiency in resource limited settings, and that the dietary surveys have generally only measured protein quantity and do not provide insight as to the quality of protein in the diets of older infants and young children."
- Average protein intakes in a number of resource-rich countries meet protein requirements, noting however that average intakes do not reflect population intake distribution data (Gibney 2004). More limited nationally representative data is available from developing countries. While *average* intakes of older infants meet protein requirements a proportion still did not meet local RDA's (noting comparison to WHO minimum levels was not published). Specific findings included
  - Philippines: 52% did not meet local protein requirements (FNRI, 2008);
  - Vietnam: 17-54% (urban & rural) (Nguyen 2013);
  - Malaysia: 7.8% (Poh et al, 2013); and
  - Indonesia: 32 -52%(urban and rural) (Sandjaja 2013).

2. <u>International trade related aspects:</u>

Codex Standards are established as a global reference point for consumers, food producers, national authorities and the international food trade. Hence the role of Codex is to generate trust and protect all stakeholders, in particular the consumer, when developing or revising Codex Standards.

Revising the protein levels of the current standard requires foremost attention to scientific substantiation, while considering also continuity of trust and international trade of Codex compliant products.

INC strongly supports ISDI's position of the provision of an overlap of the current and revised Codex Standard protein levels between 3.0 and 3.5 g/100 kcal.

The maximum proposed protein limit of 3.5 g protein/100 kcal is scientifically substantiated and also supports continuity of trust and international trade of follow-up formula for older infants compliant with the current and revised standards.

The following considerations have been taken into account in establishing the recommendation:

- The current minimum for protein defined in the Codex Standard of Follow-Up Formula (Codex STAN 156-1987) is at 3.0 g/100 kcal. As a consequence reducing the protein level to a maximum of 3.0 g/100 kcal, or lower, would **result in a mutually exclusive protein range** between the current and the revised Codex Standard.
- The implications of this **mutually exclusive protein range** would impact both consumer trust and international trade of Codex compliant follow-up formula. Stakeholders, and in particular consumers, would have to manage a complex situation for some years, given current follow-up formula may not comply with the protein requirements of the revised Codex Standard, but rather, comply with the legally binding provisions of national jurisdictions that align with the current Codex Standard. This would remain the situation until national authorities adopted the revised Codex Standard which, from experience, is known to take several years.
- A revised protein maximum that is **mutually exclusive** from existing Codex requirements would generate a significant risk of trade barriers.

- This discrepancy will likely result in confusion and a resultant lack of confidence all stakeholders without any obvious reason, and in particular by consumers, given the premise of Codex Alimentarius being the international reference point for food standards.
- In order to avoid this situation, it would make sense to adopt a maximum protein level at 3.5 g/100 kcal which, as highlighted above, is scientifically substantiated. It will also enable an overlap of current and revised Codex Standard protein levels between 3.0 and 3.5 g/100 kcal.

In conclusion, INC concurs with ISDI's reiteration that the position submitted to the 37th session of CCNFSDU, and resubmitted here, **supports a maximum protein level of 3.5 g/100 kcal,** that is both scientifically substantiated and supportive of sustained consumer trust and international trade in mutually compliant as well as nutritionally improved, safe and suitable protein requirements.

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Footnote 6
No agreement could be reached on the inclusion of footnote 6. Please state whether footnote 6 should be included, and if so whether this refers to non-hydrolysed milk protein, hydrolysed protein, or both.

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

Please provide scientific justification for your response:

Summary:

INC supports the ISDI position that footnote 6 should read as follows:

> "*Follow-up formula for older infants based on milk protein and having a protein content between 1.8 or [2.0] and the minimum level of 1.65 g/100 kcal and follow up formula based on hydrolysed protein having a protein content less than 2.25 or [2] g/100 kcal should be scientifically justified and, when needed, clinically evaluated."*

INC supports the ISDI recommendation that this footnote be adopted as it defines the need for a solid scientific basis to assess the nutritional suitability and safety of use of follow-up formula for older infants with lower minimum protein levels, given protein is a critical nutrient in supporting adequate growth and development.

Rationale - Scientific substantiation:

Growth and development during infancy depends on the nutritional adequacy of the food. Protein quantity and quality are particularly critical in supporting adequate growth and development. As a consequence, scientific substantiation of infant formulas with protein levels close to the minimum are to be clinically tested to support adequate growth and development during the first months of life. It is considered appropriate to consider scientific substantiation of the protein adequacy when the protein level is close to the minimum established protein level.

The scientific substantiation should encompass the totality of all relevant scientific data and, when needed, include clinical data. In order to ensure this objective is achieved, a footnote 6 is proposed that should define the criteria for the scientific substantiation of lower protein levels of follow-up formula for older infants to be nutritionally suitable and safe for use, comparable to the footnote introduced in the Codex Standard for Infant Formula (Codex STAN 72-1981-Rev. 2007).

At the 37th session of the CCNFSDU, the use of hydrolysed protein when used in follow-up formula for older infants was questioned. Hydrolysed protein has been safely used as a protein source in follow-up formula for older infants and several studies have demonstrated that follow-up formulas based on hydrolysed protein support adequate growth of during infancy (Berseth, 2009; Vandenplas, 2016). In addition, expert authorities (EFSA, 2005) as well as regulatory authorities (e.g., EC, US FDA) have authorised formulas based on hydrolysed protein being placed on the market. As such, footnote 6 should also encompass the scientific substantiation of the nutritional suitability and the safety of use of hydrolysed protein when used in follow-up formula for older infants.

Therefore INC supports introducing a footnote 6 that would read as follows:

> "*Follow-up formula for older infants based on milk protein and having a protein content between 1.8 or [2.0] and the minimum level of 1.65 g/100 kcal and follow up formula based on hydrolysed protein having a protein content between 2.25 or [2] g/100 kcal should be scientifically justified and, when needed, clinically evaluated."*

References

Berseth CL, Mitmesser SH, Ziegler EE, *et al.* (2009) Tolerance of a standard intact protein formula versus a partially hydrolyzed formula in healthy, term infants. *Nutrition Journal*, 8:27.

EFSA (2005) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1.9 g protein/100 kcal. *EFSA Journal*, 280:1-16.

Vandenplas Y, Alarcon P, Fleischer D, Hernell O, *et al.* (2016) Should partial hydrolysates be used as starter infant formula? A working group consensus. *Journal of Pediatric Gastroenterology and Nutrition,* 62: 22–35.

Vitamin K

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

Vitamin K

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

Minimum

☒ Codex Infant Formula standard 4 µg /100 kcal 1 µg /100 kJ	☐ EFSA 1 µg /100 kcal 0.24 µg /100 kJ

Summary:

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

Rationale - Scientific substantiation:

INC supported the ISDI position submitted to the 37th session of CCNFSDU (2015) of a minimum vitamin K level of 4 µg/100 kcal. The nutritional suitability and safety of use of this minimum vitamin K level (4 µg/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

Please provide scientific justification 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	[2.4] [1.0]	-	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 Infant Formula Standard 10 mg/100 kcal 2.4 mg/100 kJ	☒ EFSA 4.0 mg/100 kcal 1.0 mg/100 kJ

Summary:

INC supports the ISDI proposal of 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.

Rationale - Scientific substantiation:

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

Please provide scientific justification to support your preferred value in square brackets:

Zinc[20)]

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	0.5	-	[1.0] or [1.5]
mg/100 kJ	0.12	-	[0.24] or [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) and ~~maximum~~ **GUL** of [1.25 mg/100 kcal (0.3 mg/100 kJ)] applies.

GUL levels

☒ Codex Infant Formula Standard 1.5 mg/100 kcal 0.36 mg/100 kJ	☐ EU 1.0 mg/100 kcal 0.24 mg/100 kJ

Summary:

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.

INC supports this higher GUL for zinc of 1.5 mg/100 kcal.

Rationale - Scientific substantiation:

INC supported the ISDI position submitted to the 37th session of CCNFSDU (2015), requesting a higher GUL level at 1.5 mg/100 kcal, which was supported by a preliminary ISDI report on technological feasibility in managing nutrient levels in follow-up formula for older infants (ISDI – CRD 11).

The final ISDI Technological Feasibility Report concerning zinc levels in follow-up formula for older infants confirms this previous request, that the GUL of zinc be increased 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.

Within footnote 20 a maximum of 1.25 mg/100 kcal is listed. Based on your response to the GUL for milk protein based formula, what should the GUL for soy protein isolate formula be?
Summary: In view of the INC support for increasing the GUL for zinc from 1.0 to 1.5 mg/100 kcal, this higher GUL would require a parallel increase in the GUL for zinc for soy protein isolate-based follow-up formula for older infants.

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)

Please provide scientific justification to support your preferred value in square brackets:

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, **[a minimum of [x% fatty acids] should be added** 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.

If added, minimum level

☒ No minimum level specified	☐ 0.3% fatty acids	☐ Other please specify:

Summary:

INC supported the ISDI position submitted to the 37th session of CCNFSDU for the optional addition of DHA and did not specify a minimum level. Although INC and ISDI recognise that national authorities have established minimum levels for DHA to be added to follow-up formula for older infants solidly based on scientific assessment, due to the variability of DHA intake in the diversified diet of older infants, the Codex Standard for Follow-Up Formula for older infants should NOT establish a minimum DHA level, but should refer consideration of minimum levels to national authorities. The introduction of a footnote is recommended.

Rationale - Scientific substantiation:

INC supported the ISDI position submitted to the 37th session of CCNFSDU (2015) that the inclusion of DHA be an optional ingredient. ISDI stated that there was scientific consensus to support the addition of DHA to follow-up formula for older infants but considered that there was neither sufficient evidence nor scientific consensus to define strict criteria for the levels of ARA, when DHA is added (ENA, 2012; EFSA, 2013; EFSA, 2014).

Therefore INC proposes a footnote be included associated with the optional addition of DHA in line with its position and scientific consensus. This states that:

Docosahexaenoic Acid[21)]

> *"21) If docosahexaenoic acid (22:6 n-3) is added to follow-up formula for older infants, the addition of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3) are optional. If eicosapentaenoic acid were to be added, its content should not exceed the content of docosahexaenoic acid."*

In response to the request whether a minimum DHA level should be introduced into the revised Codex Standard for Follow-Up Formula for older infants (Codex STAN 156-1989), several expert opinions:

- Established nutritional requirements for DHA and concluded that the dietary DHA intake may be low in older infants, consequently support supplementation of older infant's diets, including follow-up formula for older infants (AFSSA, 2010; FAO, 2010; EFSA, 2013; Koletzko, 2013; EFSA, 2014);
- recommended DHA intake levels associated with beneficial health outcomes (AFSSA, 2010; FAO, 2010; EFSA, 2014).

However, due to the global variability of dietary DHA intakes, it remains challenging to establish a global recommendation for a minimum DHA level in the Codex Standard for Follow-Up Formula for older infants.

EPA

Irrespective of whether DHA is optional or mandated, INC has a strong view that EPA should be restricted.

This is on the basis that the cheapest source of DHA is fish oils which have a relatively high content of EPA. This is evidenced by the use of such oils for DHA supplementation of adults (commonly with an EPA:DHA ratio of 1.5:1 but which can be as high as 2:1).

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

ARA

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

Therefore INC concludes that no minimum DHA level should be set and recommends that consideration for a minimum level for DHA be referred to national authorities. The introduction of a footnote would be appropriate to allow national competent authorities to establish a minimum DHA level that could potentially read as follows:

"*National authorities may establish a minimum DHA level, as appropriate for the nutritional needs*."

References

AFSSA (2010) AFSSA opinion regarding dietary nutrient recommendations for fatty acids. AFSSA – 2006-SA-0359

EFSA (2013) Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. *EFSA Journal*, 11:3408.

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

FAO (2010) Fats and fatty acids in human nutrition. A report of an expert consultation. FAO Food and Nutrition Paper 91. Rome

ISDI comments to 37th session of the CCNFSDU (2015) Review of the standard for follow-up formula (Codex STAN 156-1987). CX/NFSDU 15/37/5-Add.1

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.

If you indicated that a minimum DHA content was warranted if added, please specify whether this requirement should be placed footnote 21 or in the table.

No minimum has been indicated.

L(+) lactic acid producing cultures	
Please provide scientific justification to support your position on the inclusion of 3.3.2.4: [3.3.2.4 Only L(+) lactic acid producing cultures may be used]	
If added, minimum level	
☐ Include as per the Codex Standard for Infant Formula	☐ Strikethrough
INC is finalising its position in relation to L(+) lactic acid producing cultures.	

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

Question 1: Proposed approach

Do you have any further suggestions to the proposed approach to enable the key themes to be met?

Answer:

Summary:

ISDI's position submitted to the 37th session of CCNFSDU supported key principles for compositional requirements that should include flexibility, less prescription, consistency, key nutrients and nutritional integrity.

Compositional requirements need to be aligned with the Codex principles of developing a global standard facilitating trade of follow-up formula as defined in Section 2 of the draft revised Codex Standard for Follow-up Formula. Consequently INC considers that those key principles can be achieved by defining mandatory and optional compositional criteria.

INC and ISDI support the principle of nutrient addition under national discretion as long as it remains exceptional to address the unique nutritional needs of specific populations and maintains the principle of Codex Alimentarius.

INC supports the ISDI view that there is no justification for introducing a new category for voluntary compositional criteria.

Rationale - Scientific substantiation:

ISDI submitted to the 37th session of CCNFSDU (2015), a position that supported the following key principles in establishing compositional criteria for follow-up formula for young children: flexibility, less prescription, consistency, key nutrients and nutritional integrity.

The following considerations were taken into account in establishing these criteria:

- Flexibility to accommodate the diversity of the young child's diet and different nutritional situations;
- Less prescription as compared to the Codex Standard for Follow-Up Formula for older infants, in order to accommodate the different place and role of this product in the diet across the world;
- Key nutrients to ensure follow-up formula for young children addresses the key nutritional and dietary needs of young children globally;
- Nutritional integrity in providing key nutrients that are provided by the core ingredients from which follow-up formula for young children are manufactured, in particular milk
- Consistency aims to recognise that nutrients that are mandatory or optional for follow-up formula for older infants may, if not mandatory, also be added optionally to follow-up formula for young children.

Flexibility, global harmonisation and consistency of follow-up formula can be achieved by defining mandatory and optional compositional criteria. The mandatory compositional criteria refer to essential and/or conditionally essential nutrients for which insufficient dietary intake is generally reported in young children (e.g. iron), or that are delivered mainly by cows' milk (calcium, B12, B2). The optional compositional criteria refer to nutrients that are either essential or conditionally essential with reported adequate dietary intakes in young children or to other nutrients for which functional benefits have been demonstrated.

INC and ISDI support the principle of nutrient addition under national discretion as long as it remains exceptional to address the nutritional needs of their specific population and maintains the principles of Codex Alimentarius.

Finally, follow-up formula for young children should not only refer to cows' milk composition or being referenced as a cows' milk substitute, but rather ought to be considered as an appropriate liquid part of the diet of young children that could be used to close existing nutritional gaps. The transition from breastfeeding, combined with complementary feeding, to consuming a variety of regular family foods can lead children 12-36 months to be at greater risk of an inadequate nutrient supply, as summarised by Suthutvoravut *et al.* (2015).

References

Suthutvoravut U, Olayele Abiodun P, Chomtho S *et al*. (2015) Composition of follow-up formula for young children aged 12–36 months: Recommendations of an International Expert Group coordinated by the

Nutrition Association of Thailand and the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 67:119–132.

Question 2:

Do you have any comments on the nutrients listed for the proposed mandatory (core) compositional requirements for the global Standard for Follow-up Formula for young children (12-36 months? Please provide justification for your answer (specific questions on the individual nutrients listed above will be addressed later in the consultation paper).

Answer:
Summary:

ISDI submitted to the 37th session of CCNFSDU a position that supported mandatory compositional criteria for the following nutrients: protein, fat (including, criteria for linoleic acid, α-linolenic acid and maximum levels for trans fatty acids and saturated fatty acids), carbohydrates (including a maximum level for the addition of sugars), iron, calcium, vitamin A, riboflavin, vitamin B_{12}, vitamin D, vitamin C, zinc, iodine, and sodium.

INC and ISDI also request consideration of folic acid and vitamin C levels, particularly with regard to iron absorption.

In establishing a list of mandatory nutrients the following was considered:

- Focus on nutrients that are globally limited in a young child's diet;
- Assessment of the concept of nutritional equivalence for key nutrients present cows' milk.

Rationale - Scientific substantiation:

The request to establish mandatory compositional criteria for selected nutrients is substantiated by data that these nutrients are often identified as lacking in the diets of young children 12-36 months (Suthutvoravut, 2015).

Additionally, given milk is a key food in the diet of young children, it is proposed that these nutrients should be aligned, as far as appropriate and technologically feasible, with the nutritional profile of cows' milk.

References

Suthutvoravut U, Olayele Abiodun P, Chomtho S *et al*. (2015) Composition of follow-up formula for young children aged 12–36 months: Recommendations of an International Expert Group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 67:119–132.

Question 3:

Regarding the approach to permit national authorities to require further mandatory requirements for the composition of follow-up formula for young children, do you support the proposal that these additional nutrients be aligned with the nutrient level permissions in follow-up formula for older infants (6-12 months)?

Answer:
Summary:

The following principles should apply to consistently assess the above question about permitting national authorities to align compositional requirements for follow-up formula for older infants with those for follow-up formula for young children:

1. Dietary requirements, dietary feeding regimens and dietary intakes differ between older infants (6-12 months) and young children (12-36 months)
2. Deviation from the compositional criteria defined in the Codex Standard for Follow-Up Formula for young children should be substantiated by specific nutritional needs to cover a specific dietary nutrient gap in the diet of young children;
3. National exceptions from the Codex Standard for Follow-Up Formula for young children should remain exceptions and substantiated by point 2 in order to comply with the core principles of Codex Alimentarius.

INC and ISDI support national authorities under exception establishing compositional requirements for selected nutrients for follow-up formula for young children similar to those defined for follow-up formula for

older infants, if these exceptions are scientifically substantiated and do not oppose core Codex Alimentarius principles.

Question 4: Optional addition of nutrients/ingredients/substances

Do you agree that any optional nutrient/ingredient/substance addition should only be permitted if this nutrient/ingredient/substance is permitted in follow-up formula for older infants? Do you agree that the level of addition of any optional nutrient/ingredient/substance should be as specified in the Standard for Follow-up Formula for older infants? Please provide specific examples if you think amendments are necessary.

Answer:
Summary:

INC supported the ISDI position submitted to the 37th session of CCNFSDU which supported the core principles for addition of optional ingredients to be similar for both follow-up formula for older infants and for follow-up formula for young children.

However, at the 37th session of the CCNFSDU it was agreed that optional ingredients should comply with the following requirement defined in paragraph 3.3.2.2:

> "*When any of these ingredients or substances are added, the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk."*

INC and ISDI seek clarification regarding the interpretation of "*taking into account levels in human milk*" and whether this implies that only ingredients or substances present in human milk and at human milk levels would be authorised to be added, independent of the criteria defined in paragraph 3.3.2.1.

INC and ISDI are of the opinion that reference to human milk should be interpreted as inclusive, **but not exclusive**, of substances and ingredients that are safe and suitable for use by young children, added at a level of use that is evaluated and demonstrated safe and suitable by generally accepted scientific evidence, as defined in 3.3.2.1.

Clarification should therefore be provided and, as needed, adapted to reflect the above considerations when incorporated into the Codex Standard for Follow-Up Formula for young children.

Furthermore, permission to add an optional ingredient to Follow-up formula for young children should not be limited by permission to add these ingredients to Follow-up formula for older infants. AND

The concept of reference criteria for selected optional nutrients not be mandated in the Standard (e.g. vitamins and minerals), including those that National Authorities may wish to mandate under exception, in order to allow for a harmonised approach. This list should not be considered exhaustive.

As outlined earlier, reference criteria nutrient limits should not automatically default to limits permitted for Follow-up formula for older infants. For example:

- Phosphorous – the GUL proposed for phosphorus for 6-12 month olds of 100mg/100kcal may be too low. The GUL for phosphorus will need to be >=100mg/100kcal to achieve a calcium:phosphorous ratio<=2.
- Further consideration will also need to be given to inherent cows' milk vitamin and mineral ranges, as the higher maximum of 12-36 month products will deliver higher levels of naturally present nutrients than 6-12 month where the maximum is significantly lower.

Question 5: Protein

Please provide comment (with justification) on whether particular compositional requirements for protein should be included in the Standard for Follow-up Formula for young children, and if so, please specify your recommendation.

Answer:
Summary:

INC supported the ISDI position submitted to the 37th session of CCNFSDU for the inclusion of protein requirements, namely a minimum level and a GUL, in the Codex Standard for Follow-Up Formula for young children.

In establishing protein requirements, INC considers that all of the following should be taken into account: upper safe protein intake levels, dietary protein intake levels (including population intake distribution), protein quality and history of apparent safe use as well as global implications of the recommendations. This will be challenging given the diversity of dietary practices and needs across the globe as well as considerations regarding the protein content of cows' milk, generally considered as the reference point for follow-up formula for young children.

In conclusion, INC supports the ISDI view that given all these facts, broader rather than narrow criteria should be established for protein requirements for Follow-up Formula for young children.

Question 6: Protein

Is there a need to include a maximum level or GUL, or not specified, for protein in follow-up formula for young children? Please provide justification for your answer.

Answer:
Summary:

INC considers that prior to defining whether a maximum level, GUL or not specified level is most appropriate for the Codex Standard for Follow-Up Formula for young children, it is most relevant to consider establishing the upper safe protein level.

Question 7: Protein

If the Standard for Follow-up Formula for young children was to allow for fortified milk products, how should the Standard accommodate this? Particularly with regards to the protein content of cows' milk.

Answer:
Summary:

INC concurs with ISDI, that follow-up formula for young children is different from a fortified milk, given the latter could include milk with the addition of only one of two vitamins.

INC concurs with ISDI that the Codex Follow-up Formula Standard for young children should continue to encompass formulas predominately based on milk, that also meet the other mandatory compositional requirements of the Standard (e.g. vitamin A, vitamin D, vitamin B_{12}, calcium, iron, zinc).

Question 8: Fat

Please provide comment (with justification) on whether particular compositional requirements for fat should be included in the Standard for Follow-up Formula for young children, and if so, please specify your recommendation.
Consideration should be given to: the need for minimum/maximum total fat requirements, fatty acid requirements, and limits on use of commercially hydrogenated oils and trans fat.

Answer:
Summary:

INC generally supported the ISDI position submitted to the 37th session of CCNFSDU for mandatory compositional criteria for fat, namely total fat (minimum and maximum), criteria for linoleic acid and α-linolenic acid.

In addition, INC considers that the compositional criteria should enable sufficient flexibility to accommodate nutritional requirements, dietary fat intake levels, fat quality, milk fat compositional criteria (e.g., milk fat trans-fat levels) and history of apparent safe use as well as global implications of the recommendations.

Question 9: Carbohydrate

Please provide comment (with justification) on whether particular compositional requirements for carbohydrate should be included in the Standard for Follow-up Formula for young children, and if so, please specify your recommendation?

Answer:
Summary:

INC supported the ISDI position submitted to the 37th session of CCNFSDU for mandatory compositional criteria for carbohydrates, in particular reducing the addition of sugars.

Additionally, INC considers that the compositional criteria for carbohydrates should be developed alongside the energy requirements, enabling a nutritionally adequate balance between protein, fat and carbohydrates.

INC considers it imperative to define sources and quality of carbohydrates that can be used in the Codex Standard for Follow-Up Formula for young children. Particular focus should be given to limiting the addition of sugars (mono- and disaccharides), excluding lactose which should be the preferred carbohydrate, given it is naturally present and abundant in cows' milk.

Question 10: Iron

Do you support the inclusion of iron as a mandatory nutrient addition to follow-up formula for young children (12 – 36 months)? If so, please state whether you support alignment with the range of 1.0-2.0 mg/100 kcal as recommended for follow-up formula for older infants.

Answer:
Summary:

INC supported the ISDI position submitted to the 37th session of CCNFSDU for mandatory compositional criteria for iron. In addition, INC supports a broader range for iron in follow-up formula for young children compared to the range proposed for older infants.

Rationale - Scientific substantiation:

The importance of combatting dietary iron deficiency is generally supported. Despite this common understanding, iron deficiency is still a global nutritional problem.

In Europe, dietary intakes of iron are low in young children and EFSA has recommended that particular attention is paid to ensuring an appropriate supply in those with inadequate intake or at risk of inadequate intake (EFSA, 2013).

On a global level, iron has been identified as a problematic nutrient based on national or community-based intake surveys of young children (Suthutvoravut, 2015). Furthermore, the necessity to improve the dietary supply of iron to older infants and young children has been highlighted by the WHO (2013).

On average, cows' milk and milk-based product contains very low levels of iron (< 0.1 mg/100kcal) (EFSA, 2012) and the potential for iron deficiency is considerable if cows' milk or milk-based products are the main protein sources of the young child's diet when comparing the WHO recommended nutrient intakes for iron (5.8 mg/day).

To close this nutritional gap, INC and ISDI support the inclusion of iron as a mandatory nutrient in follow-up formula for young children. In addition, INC supports a broader range for iron in follow-up formula for young children compared to the range proposed for follow-up formula for older infants.

References

EFSA (2013) Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. *EFSA Journal*, 11:3408.

Suthutvoravut U, Olayele Abiodun P, Chomtho S *et al*. (2015) Composition of follow-up formula for young children aged 12–36 months: Recommendations of an International Expert Group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 67:119–132.

WHO (2013) WHO Guidelines approved by the Guidelines Review Committee: Essential nutrition actions: Improving maternal, newborn, infant and young child health and nutrition. Geneva, World Health Organization.

Question 11: Nutritional equivalence with key nutrients

How should the compositional parameters for follow-up formula for young children be flexible enough to allow for nutritional equivalence with key nutrients in cows' milk?

Answer:
Summary:

INC and ISDI support mandatory compositional criteria for a selected number of nutrients for follow-up formula for young children. The criteria to identify these selected nutrients includes, amongst others, their presence in cows' milk and the contribution of cows' milk to the dietary intake of these nutrients in the diet of young children.

Therefore INC and ISDI are of the opinion that calcium, riboflavin, vitamin B_{12}, vitamin A and zinc should be included in the mandatory list.

We consider that nutritional equivalence for these nutrients should be aligned, as far as appropriate and technologically feasible, with the nutritional profile of cows' milk.

References

Suthutvoravut U, Olayele Abiodun P, Chomtho S *et al*. (2015) Composition of follow-up formula for young children aged 12–36 months: Recommendations of an International Expert Group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 67:119–132.

Question 12: Calcium

Do you support the inclusion of calcium as a mandatory nutrient addition to follow-up formula for young children (12 – 36 months)?

Answer:
Summary:

INC and ISDI consider that milk and milk-based products are good sources of calcium for young children. Follow-up formula for young children, generally milk-based, should therefore also be a good source of calcium, as it is often considered as a substitute for milk or milk-based products.

As a consequence, calcium should be a mandatory nutrient for follow-up formulas for young children.

Question 13: Calcium

If you supported the inclusion of calcium as a mandatory nutrient addition, please state what mandatory requirements are necessary, for example is a range required? Maximum or GUL?

Answer:
Summary:

Establishing calcium as a mandatory nutrient in follow-up formula for young children requires careful assessment of the relevant and implementable nutrient levels for calcium. In defining calcium levels for follow-up formula for young children, consideration has to be given to

1) nutritional requirements for young children;
2) benefits of calcium supplementation;
3) technological feasibility of calcium supplementation.

Points 1) and 2) have been documented previously by several delegations. Point 3) regarding the technological aspects of calcium supplementation are more complex given the interaction between protein and calcium. These are elaborated in the ISDI report regarding technological feasibility for follow-up formula for young children (ISDI, 2016).

INC concurs with the ISDI recommendation that a Ca:Protein ratio be specified.

An imbalance in the Ca:Protein intake ratio has been shown to lead to secondary hyperparathyroidism and bone loss. Maintaining a balanced intake (1:1.2) reduces post-prandial peaks in PTH (Uribarri and Calvo, 2013).

References

ISDI Report (2016) Technological aspects relating to the establishment of nutrient ranges in follow-up formula for young children (12-36 months) (Codex STAN 156 – 1987). 17 February 2016.

Uribarri J and Calvo MS. 2013. Dietary phosphorus excess: a risk factor in chronic bone, kidney, and cardiovascular disease? Adv Nutr 4:542-544.

Question 14: Vitamin A

Do you agree that vitamin A should be mandated in follow-up formula for young children (12-36 months)? If you support the addition of vitamin A to follow-up formula for young children, please propose a level for addition – min/max/GUL.

Answer:
Summary:

INC and ISDI support establishing vitamin A as a mandatory nutrient of follow-up formula for young children.

Vitamin A requirements are proposed at a minimum of 50 µg RE/100 kcal and a GUL at 200 µg RE/100 kcal. This range for vitamin A will enable nutritional requirements to be met, and provide for upper safe intake levels as well as technological feasibility aspects of vitamin A.

Question 15: Further comments

Do you have any further comments on the proposed approach that you would like the Chairs to consider in formulating the 2nd Consultation Paper?

Answer:
Summary:

INC supports the establishment of compositional criteria for follow-up formula for young children within the context of the whole young child's diet, and with the aim of closing the nutritional gaps that often exist in this age group.

The assessment should consider the needs and differences between both developing and developed countries.

INC would argue against follow-up formula for young children being seen as the sole source of nutrition or the primary/main source of the liquid diet.

Finally follow up formula for young children has to be considered as a substitute to cows' milk and therefore needs to provide the key nutrients that are provided by cows' milk, as far as appropriate and technologically feasible.