REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156-1987)

(Chaired by New Zealand and co-chaired by Indonesia and France)

Second Consultation Paper
Submitters Response Form

June 2016

Please respond by **19th July 2016**

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Name of Member Country/Organisation: _____ ISDI _____

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

In your responses to the following section please provide scientific justification for your response and where possible, references for the scientific rationale.

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

Please provide scientific justification and applicable references to support your response:

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 requirements for the majority of this age group.

Based on the totality of the evidence, and in particular new data, and while recognizing the debate within the scientific and regulatory community regarding the adequate lower protein level for follow-up formula for older infants is ongoing, ISDI recommends to adopt a lower minimum protein level at 1.65 g/100 kcal

similar to the requested level at the 37th session of CCNFSDU.

As substantiated in the next section a footnote should accompany the protein level, to ensure that any formula containing protein between 1.65 and 1.8g/100kcal is 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 are based on maintenance of requirements of 0.66 g/kg bodyweight per day and a protein efficiency utilization 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 compared to previous estimates primarily as a result of changes in the reference body weights 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 older infants (6-12 months) calculated from WHO/FAO/UNU protein requirements (WHO/FAO/UNU 2007) using WHO weight-for-age growth standards (WHO 2006) result in an average of 10.2 g protein/day.

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 the PRIs of 1.31 and of 1.14 g protein /kg at 6 months and 12 months, respectively as described above (Koletzko, 2013). Therefore, the ENA (Koletzko, 2013) recommends setting the minimum protein level of cow's 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 to be taken into consideration. The results of these dietary surveys have consistently identified that average protein intakes in this age group are above recommended intakes, which suggests adequate protein intakes for a majority of infants and young children (Agostoni, 2006). Studies showed that infants and young children have average protein intakes above recommended dietary requirements in France (mean intakes 17.8g/day at 6 months) (SFAE, 2014) or USA (mean intakes 19g/day between 6-11 months) (Butte 2010). 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; Sandja, 2013) – up to five times higher than the WHO/FAO/UNU safe intake level.

Finally, ISDI considers 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. Indeed two recent randomized clinical trials demonstrated adequate growth and development. Ziegler et al. (2015) reported that infants receiving a formula 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). In a follow-up of the study, the results were confirmed at 5 years of age (Ziegler 2015b). Similarly, Inostroza et al. (2014) demonstrated that infants born to overweight mothers receiving a formula with 1.65 g protein/100 kcal from age 3 to 12 months have adequate growth and growth rate similar to that of breastfed infants

In order to confirm their safety and suitability ISDI recommends that formulas containing protein between 1.65 and 1.8g/100kcal should be scientifically substantiated, and when needed, clinically evaluated prior to placing on the market. Therefore ISDI recommends a footnote should accompany the minimum protein level.

In conclusion, based on the available data, in particular the data from clinical trials published in the last years, and consistent with ISDI's recommendation to the 37th session of CCNFSDU, ISDI requests the 38th session of CCNFSDU to consider adopting a minimum protein level of 1.65 g/100 kcal. However, in order to assure follow-up formulas for older infants containing protein between 1.65 and 1.8g/100kcal between are sufficiently substantiated, ISDI recommends that a footnote be introduced requesting scientific substantiation and clinical evaluation when needed (see below).

References

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

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Inostroza J, Haschke F, Steenhout P, *et al.* (2014) Low-protein formula slows weight gain in infants of overweight mothers. *Journal of Pediatric Gastroenterology and Nutrition*, 59:70-77.

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Nguyen BKL, Thi HL, Do Van *et al.* (2013) Double burden of undernutrition and overnutrition in Vietnam in 2011: results of the SEANUTS study in 0.5-11 year old children. *British Journal of Nutrition*, 110:S45-56.

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Ziegler EE, Fields DA, Chernausek SD *et al.* (2015) Adequacy of infant formula with protein content of 1.6 g/100 kcal for infants between 3 and 12 months. *Journal of Pediatric Gastroenterology and Nutrition*, 61:596-603.

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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

Please provide scientific justification and applicable references for your response:

Summary

Similarly to its position submitted to the 37th session of CCNFSDU and the eWG first consultation paper of 2016, ISDI supports 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, ISDI reiterates its previously submitted comments in support of the scientific and general substantiation of a maximum protein level of 3.5 g/100 kcal.

ISDI would like the 38th session of CCNFSDU to consider adopting 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 regarding 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 becomes a challenging exercise for most nutrients. Indeed both minimum and maximum safe and suitable nutritional requirements require tailoring to each geographical, national or dietary setting, which from a global perspective is less than uniform. As a consequence setting of minimum and maximum levels, particularly for protein must balance these considerations.

The ISDI position submitted to the 37th session of CCNFSDU, supporting a maximum protein level of 3.5 g/100kcal, was substantiated. ISDI reiterates specifically 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. To this aim ISDI focused on scientific experts opinions regarding upper safe protein intake levels. Both EFSA (2014) and WHO/FAO (2007) did not 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 follow-up formulas with protein at this level have been globally marketed since the origin of the Codex Standard for Follow-up Formula (Codex STAN 156-1987).

   ISDI took the following considerations into account in establishing its 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.
- The 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*".
- The WHO/FAO (2007) also emphasizes 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. Indeed, European data indicated 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) reported 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.
- Considerations should be given to the diversity of protein intakes across the globe in establishing the maximum protein level, which should take into account the protein intakes of older infants living in both 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). Fewer nationally representative data are 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, 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 international food trade. Hence its role 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 the scientific substantiation but consideration must also be given to the continuity of trust in Codex Alimentarius and international trade of Codex compliant products.

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.

ISDI took the following considerations into account in establishing its 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 approach would be both impacting consumer trust and international trade of Codex compliant follow-up formula. Indeed stakeholders, and in particular consumers, will 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 comply with the legally binding provisions by national jurisdictions that align with the current Codex Standard. This situation would persist for some years until national authorities adopt the revised Codex Standard. Out of experience this is known to take a few years and is not a synchronized process.

- This discrepancy, of mutually exclusive permitted protein ranges in the revised compared to the existing Standard, will likely result in confusion and a resultant lack of confidence. All stakeholders will potentially be affected, and in particular consumers, given the premise of Codex Alimentarius being the international reference point for food standards, most importantly without any obvious reason.
- In order to avoid this happening 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.
- A revised protein maximum that is mutually exclusive from existing Codex requirements would generate a significant risk of trade barriers.

In conclusion, ISDI reiterates that its position submitted to the 37th session of CCNFSDU, and resubmitted at present, supports a maximum protein level of 3.5 g/100 kcal, that both is scientifically substantiated and supportive of sustained consumer trust and international trade .

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Footnote 3

Refers to the requirements of essential and semi-essential amino acids in follow-up formula:

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

At present the draft standard does not contain an Annex I, please indicate whether you support inserting Annex I of the Codex Standard for Infant Formula of if you consider that further work is required.

☐ insert Annex I (or refer) to the Codex Standard for Infant Formula	☒ review the levels contained within the Codex Standard for Infant Formula.

If you consider that a review is required, please indicate the basis for this review.

ISDI would like the 38th session of CCNFSDU to consider reviewing the requirements of essential and semi-essential amino acids in follow-up formula. Although new data on human milk amino acid data (Zhang, 2013; Lönnerdal, 2016) suggest consistency with previously reported data, ISDI appreciates the eWG to take the new data into consideration when reviewing amino acid requirements.

ISDI acknowledges that protein quality for the essential composition of follow-up formula is of key importance and that defining minimum levels for amino acids using the amino acid composition of breast milk as a reference would address this concern. However since the publication of the Codex Standard for Infant Formula and its Annex I, new publications have described the amino acid profile in human milk including recent systematic reviews (Zhang 2013, Lönnerdal 2016) and should be considered.

In addition, Annex I of the Codex Standard for Infant Formula describes the levels of essential and semi-essential amino acids expressed per g of nitrogen, per g of protein and per 100kcal. The average level of an amino acid (mg per g of nitrogen) from each study described in Annex I was used to calculate the corresponding amino acid content per 100 kcal of an infant formula with the minimum protein content of 1.8 g/ 100 kcal accepted in this Standard (mg amino acid/g nitrogen in breast-milk divided by the nitrogen conversion factor of 6.25 and multiplied by 1.8).

If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for follow-up formula for older infants, new calculations should be made using a factor of 1.65 instead of the factor of 1.8 currently used in Annex I of the Codex Standard for Infant Formula.

References

Lönnerdal B, Erdmann P, Thakkar Sagar K *et al.* (2016), Longitudinal evolution of true protein, amino acids, and bioactive proteins in breast milk: A developmental perspective. *The Journal of Nutritional Biochemistry*, 2016.06.001.

Zhang Z, Adelman AS, Rai D et al. (2013) Amino acid profiles in term and preterm human milk through lactation: a systematic review. *Nutrients,* 5:4800-4821.

Footnote 6

The majority of the eWG supported retaining elements of footnote 6.

[6)]Follow-up formula based on ~~non-hydrolysed~~ **intact** milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated

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

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

Please provide justification for your response.

ISDI considers that intact as well as hydrolysed protein has been safely used as a protein source in follow-up formula for older infants. Indeed several studies have demonstrated that formulas based on hydrolysed protein support adequate growth during infancy (Berseth, 2009; Vandenplas, 2016).

As such ISDI considers the 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 at low level.

In conclusion, the footnote should read:

[6)]Follow-up formula based on intact milk protein containing [less than 1.8g protein /100Kcal] or [between 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated **when needed.**]

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.

Vandenplas Y, Alarcon P, Fleischer D, *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.

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

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

☐ intact milk protein	☒ non-hydrolysed milk protein

Please provide justification for your response.

For the sake of clarity and as better defined than intact milk protein, ISDI proposes to align with Codex Standard for Infant Formula (CODEX STAN 72 – 1981, rev.2007) and use the wording “non-hydrolysed protein”.

Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required for any formulas based on intact/non-hydrolysed milk protein?		
☒ Yes, all formulas containing 1.65-1.8 g/100 kcal require clinically evaluation	☐ Yes, all formulas containing 1.65-2.0 g/100 kcal require clinically evaluation	☐ no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal

Please provide justification for your response.

ISDI is of the opinion that all formulas containing a protein content between 1.65 and 1.8g/100kcal should be scientifically substantiated, and **when needed**, clinically evaluated. This will confirm their safety and suitability.

ISDI considers that follow-up formula for older infants containing a protein level between 1.8 g and 2.0 g/100 kcal do not require clinical evaluation, in agreement with a recent EFSA assessment (EFSA, 2014). The EFSA opinion concluded that the scientific data is sufficient to prove the safety of all formulas (infant and follow-on) manufactured from intact milk protein with a protein content higher than 1.8 g/100 kcal.

Reference

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

If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for formula based on intact/non-hydrolysed milk protein, do you support the recommendation that the minimum protein level which requires clinical evaluation is placed in the footnote, rather than in the table? See **Error! Reference source not found.** above	
☐ Yes	☒ No

ISDI favours that this reference be put in the table.

Vitamin K

Vitamin K

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

Vitamin K

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

Please comment on this proposal and provide your justification:

Summary

In continuation of the ISDI position submitted to the 37th session of CCNFSDU as well as the answer to the eWG first consultation paper, ISDI supports a minimum vitamin K level at 4 µg/100 kcal. ISDI would like the 38th session of CCNFSDU to consider setting the 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

In the ISDI position submitted to the 37th session of CCNFSDU (2015), a minimum vitamin K level at 4 µg/100 kcal was supported.

Additionally, the nutritional suitability and safety of use of a minimum vitamin K level at 4 µg/100 kcal for follow-up formulas for older infants has most recently been 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.

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

Vitamin C

Vitamin C

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

Vitamin C[15)]

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

[15)] expressed as ascorbic acid

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

Minimum levels

☐ Codex IF Standard 10 mg/100 kcal 2.5 mg/100 kJ Taking a precautionary approach and aligned with the Codex Infant Formula Standard	☒ EFSA 4 mg/100 kcal 0.96 kJ/100 kcal Based on vitamin C requirement levels established by EFSA, taking into account that complementary foods are consumed from six months.

Please provide your preferred response:

Summary

Similarly to its position submitted to the 37th session of CCNFSDU as well as the answer to the eWG first consultation paper, ISDI supports a minimum vitamin C level at 4 mg/100 kcal. ISDI would like the 38th session of CCNFSDU to consider setting the 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

In the ISDI position submitted to the 37th session of CCNFSDU (2015), a minimum vitamin C level at 4 mg/100 kcal was supported.

Additionally, 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 has most recently been substantiated by the EFSA assessment regarding vitamin C compositional requirements for follow-on formulas in the European Union (i.e. follow-up formula for older infants) (EFSA, 2014).

References

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

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

Zinc

Zinc

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

Zinc

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

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

Please comment on this proposal and provide your justification:

Summary

ISDI supports the proposed composition requirements for zinc. This is in line with ISDI's position expressed in the eWG first consultation paper as supported by the final ISDI report on the technological feasibility.

Rationale - Scientific substantiation

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

The final ISDI report regarding the technological feasibility of zinc levels in follow-up formula for older infants confirms the previous request by ISDI to the 37th CCNFSDU to increase the GUL of zinc from 1.0 to 1.5 mg/100 kcal, based on preliminary data. Setting the GUL for zinc at 1.5 mg/100 kcal is supported by data regarding the history of apparent 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.

In conclusion, ISDI reiterates its previously made proposal for a GUL for zinc of 1.5 mg/100 kcal, based on data regarding the technological feasibility as well as the recommendation of the International Expert Group coordinated by the Early Nutrition Academy (Koletzko, 2013). Moreover, this proposal is scientifically and technologically substantiated and accommodates all the principles defined by Codex Alimentarius.

References

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

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

of ISDI.

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

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

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)			
No consensus was reached on the need for a minimum level, as a compromise could you accept that a statement is included in the footnote stating that national authorities can establish minimum requirements for the optional addition of DHA at their discretion. **Docosahexaenoic acid[21)]** **Unit** / **Minimum** / **Maximum** / **GUL** % fatty acids / [-] or [0.3] / - / 0.5 **21)** If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.			
☒ Yes	☐ No		

Summary

ISDI reiterates its position shared in CP1, namely a) support for the optional addition of DHA, b) no specific minimum level and c) no mandatory addition of ARA when DHA is added, which is to be appropriately reflected in the footnote.

As stated in CP1, ISDI recognizes that national authorities have established minimum levels for DHA to be added to follow-up formula for older infants solidly based on scientific assessment. Against this background, ISDI reiterates its position that, 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 refers considerations regarding minimum levels to national authorities. The introduction of a footnote is recommended.

Rationale - Scientific substantiation

In the ISDI position submitted to the 37th session of CCNFSDU (2015), ISDI supported the inclusion of DHA as an optional ingredient; "*ISDI considers that there is scientific consensus to support the addition of DHA to follow-up formula for older infants. However, ISDI considers that on the contrary there is at 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).*"

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), ISDI takes into consideration that several expert opinions have:

- 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 ISDI also emphasizes that is indispensable to consider that due to the global variability of dietary DHA intakes, it remain challenging to establish a global recommendation for a minimum DHA level in the Codex Standard for Follow-Up Formula for older infants.

In conclusion, ISDI considers that no minimum DHA level should be set and recommends that considerations regarding a minimum level for DHA be referred to national authorities. The introduction of a footnote would be appropriate to accommodate national competent authorities to establish a minimum DHA level and could potentially read as follow "*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.

Optional Ingredients: L(+) lactic acid producing cultures

Optional addition L(+) lactic acid producing cultures		
[3.3.2.4 Only L(+) lactic acid producing cultures may be used]		
Several eWG members noted there are two purposes for the addition of L(+) lactic acid producing cultures referring to both the acidification of formula and supplementation with probiotics. Please indicate if you consider that the sub-Section 3.3.2.4 (Optional ingredients) should refer to one, or both types of addition.		
☒ Two purposes: acidification of formula **and** supplementation with probiotics	☐ For the purpose of acidification of formula **only**. Contains minimal amounts of viable bacteria.	☐ For the purpose of supplementing with probiotics **only**
Please provide justification for your preferred response: ISDI considers that the standard should refer to both types of addition: L(+) lactic acid producing cultures may be added for acidification purposes. In that case, formula are fermented with the help of L(+) lactic acid bacteria (formula in which lactose is converted into lactic acid) during the production process. L(+) lactic acid bacteria are no longer active in the finished products as they are subject to heat treatment. The addition of bacteria for the purpose of conferring other outcomes that may be broadly categorized as "for nutritional purpose" fall under substances added as optional ingredients. Such cultures, including but		

not limited to L(+) lactic acid producing cultures, may only be added if they meet the requirements of optional ingredients.

If you consider that standard should allow for both types of addition, please indicate if you think that this should be captured within 3.3.2.4, or as two separate clauses within the Optional Ingredients Section (Section 3.3.2).

ISDI is of the opinion that both types of addition should be addressed in two separate clauses within the Optional Ingredients section (section 3.3.2):

- Section 3.3.2.4 should be kept for acidification: “Only L(+) lactic acid producing cultures maybe used for acidification.”
- Plus a new clause which can be 3.3.2.5 and would stipulates that “Other bacterial strains may be used for nutritional purpose when demonstrated safe and suitable in accordance with the general principles that are listed in the sections 3.3.2.1 and 3.3.2.2 relative to optional ingredients in the Standard”

Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.

☒ The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence
☐ Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria
☒ For the purpose of producing acidified formulas
☒ Non-pathogenic lactic acid cultures may be used
OR
☐ No additional wording is required. Alignment with the Codex Infant Formula Standard

Please provide justification for your response and any proposed draft text:

It should be clear in the optional ingredients section that bacteria may be added for the two purposes outlined above. L (+) lactic acid producing bacterial strains and other cultures may also be added for other purposes.

Bacterial cultures added for purposes other than acidification are optional Ingredients and they must meet the criteria set-out that apply to all optional ingredients and recommends the addition of text that makes this clear. These criteria encapsulate the additional concepts recognised as important and ticked above of safety (including non-pathogenicity) and suitability, evaluated and demonstrated by generally accepted scientific evidence, without need for re-stating.

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

Proposed approach

Mandatory (core) composition
Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is : • Evidence to support nutritional issues for young children of global concern; • Contribution to the overall nutritional quality/integrity of the product; • The contribution of key nutrients from cows milk for equivalence; and • The strength of committee support for including in the core composition.
Answer: **Summary – ISDI approach** In terms of establishing compositional requirements of follow-up formula for young children as a liquid part of the diversified diet, the primary objective should be to contribute to the nutritional needs of young children. This primary objective can be achieved by considering the following; 1) effectively support the nutritional needs of young children globally, 2) address globally relevant dietary nutrient inadequacies, 3) take into account the key nutrient levels provided by cow's milk and 4) maintain the nutritional integrity of the product. While each nutrient is assessed on a case by case basis, the compositional criteria should always take these principles into consideration. **Energy:** ISDI supports an energy range of 45-70 kcal/100 mL, noting this range incorporates energy levels of reduced fat and whole milk, and results in a 15-22% contribution to total daily energy needs for an average 300 mL consumption. **Macronutrients:** ISDI provides justification for macronutrient ranges in each respective question box below. **Micronutrients:** ISDI provides justification for micronutrient ranges in each respective question box below. In addition to the general approach, we also considered safety and technological feasibility associated with manufacturing in establishing nutrient ranges, similar to the principles outlined in Annex II of the Codex Standard for Infant Formula (CX-STAN 72-1981). Minimum levels were calculated on the basis of a 300mL serve contributing 30% to the eWG suggested NRV's, with the exception of calcium where the minimum level is linked to protein level and will be confirmed after protein levels are defined. Maximum or GUL levels were calculated on the basis of 300mL contributing <50% of the UL **or** 3-5 fold the minimum levels. This is aligned with the GUL principle explained in Annex II of the Codex Standard for Infant Formula (CX-STAN 72-1981). For nutrients that have safety concern regarding a maximum and for nutrients where no evidence of safety concerns for an upper limit are established, a GUL is proposed.

ISDI supports **mandatory compositional criteria for the following nutrients**:

- Energy
- Protein
- Fat, including specifications for linoleic acid, α-linolenic acid and trans fatty acids
- Carbohydrates, including maximum levels for total carbohydrate and added sugars
- Vitamins and minerals: iron, calcium, vitamin A, riboflavin, vitamin B_{12}, vitamin D, vitamin C, zinc, iodine, sodium and folic acid.

ISDI notes that the eWG has not included iodine and folic acid on the mandatory list – as proposed in the ISDI reply to CP1 – and asks that consideration is given to both of these nutrients.

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

Answer:

ISDI does not support the need to identify a minimum number of principles.

As per comments in the previous section, ISDI considers that the following criteria are critical in establishing which nutrients are to be set as mandatory for follow-up formula for young children:

- effectively support to the nutritional needs of young children globally;
- address globally relevant dietary nutrient inadequacy;
- take into account the key nutrient levels provided by cow's milk, and;
- maintain the overall nutritional integrity of the product.

While each nutrient is assessed on a case by case basis, the compositional criteria should always take these principles into consideration, as already outlined in our response to CP1, including the overarching principles of increased flexibility and less prescription.

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

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

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

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

Answer:
Please provide justification for your answer:

As outlined in the response to CP1, ISDI does not support the proposed approach for the "voluntary nutrient additions." The introduction of this proposed new category of nutrients adds unnecessary complexity to the standard. If it is considered appropriate by a national authority to mandate the addition

of nutrients for follow-up formula for young children where not mandated in the standard, ISDI recommends that these nutrients follow the principle of optional ingredients.

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

Answer:
Please provide justification for your answer:

ISDI notes that the eWG is endeavouring to provide a framework for national authorities to mandate additional nutrients where considered appropriate to address local nutrient inadequacies. As stated above, ISDI considers that the requirements for optional ingredients should apply and that limits set for additional locally mandated ingredients need to take into account safety and suitability, the levels in milk and technical feasibility. ISDI recommends against simply adopting the limits applied for follow-up formula for older infants as default limits as these will not always be appropriate.

Optional Ingredients

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

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

Answer:
Please provide justification for your answer:

ISDI supports the core principles for addition of optional ingredients.

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

Answer:
Please provide justification for your answer:

ISDI is of the opinion that follow-up formula for young children should not refer to levels in human milk but should rather substantiate the significant level of the nutrient when added. Hence, ISDI supports deletion of the sentence between brackets.

QUESTION: Do you support deletion of the third bullet point for follow-up formula for young children?
Answer: *Please provide justification for your answer:* ISDI can support the deletion of the list of examples to apply principles as proposed by the eWG Chair; noting that this list is not a closed list.

Energy contribution from macronutrients

Energy contribution from macronutrients
Please provide comment and justification as to whether it is necessary to define specific macronutrient percentage contribution to overall energy.
Answer: ISDI supports an approach that mandates the energy range of the product and levels for macronutrients based on the key principles. The proposed levels in g/100 kcal are equivalent to using percentage of energy from macronutrients. To determine the g/100kcal of each macronutrient, ISDI took into account the different energy densities of formulations (45-60-70 kcal). The conclusions are summarised in Table 1 below; the justification for the nutrient ranges are outlined in each respective question box.

	Range %E	**g/100kcal**
Protein	6-22%	1.5-5.5 g
Fat	32-54%	3.5-6 g
Carbohydrate	NA	<TBD

Table 1. ISDI conclusions on energy contribution from macronutients to overall energy

Energy

Energy		
Members of the eWG have recommended that the energy density of follow-up formula for young children should be established, and the following levels proposed: **Energy**		
Unit	**Minimum**	**Maximum**
kcal/100 ml	[60] [45]	[70]
kJ/100 ml	[250] [188]	[293]
Should the range for the energy density of follow-up formula for young children accommodate the energy content of full fat cows' milk *and* reduced fat cows' milk, or align with the minimum energy density of follow-up formula for older infants?		
☐ FUF-older infants & full fat cows' milk 60 kcal/100ml 250 kJ/100 ml		☒ Reduced fat cows' milk (~1.5-2% fat) 45 kcal/100 ml 188 kJ/100 ml
Please provide justification for your answer		

The minimum energy is set as the approximate energy density of reduced fat cows' milk (~1.5-2% fat), 45 kcal/100 mL.
Do you support establishing a maximum energy density for follow-up formula for young children? If so, do you have suggestions as to how this level should be derived?
Answer: The maximum energy is set as the approximate energy density of whole cows' milk, 70 kcal/100 mL. ISDI recommends that a maximum level is set for energy as this is key to ensuring that ranges specified for individual macro- and micronutrients reflect the optimal levels sought on an energy basis. Energy range of 45-70 kcal/100 mL is considered appropriate based on both the reference to cow's milk as well as to making a relevant contribution of approximately 15-22% of the daily dietary energy intake of young children when an average 300mL serve is considered, as per WHO (2005) guidelines for milk consumption in 6-24month children. The energy range set needs to allow flexibility for protein reduction to be offset by a mix of increased fat and carbohydrate and not just by increased carbohydrate. ISDI considers this to be very important or the outcome could be product formulations with very high levels of carbohydrate *Reference* WHO (2005) Guiding Principles for feeding of non-breastfed children 6-24 months of age. World Health Organization: Geneva.

Protein

Protein
Considering the eWG's varied views, are minimum and maximum requirements necessary? If so, please state your preferred approach on how to establish protein requirements?
Please provide justification for your answer
Should there be requirements for protein quality? If so how this might be achieved? Please consider both the current Follow-up formula standard, and proposals within the draft standard for older infants.
Please provide justification for your answer: **General commentary** ISDI recommends that minimum and maximum protein levels are established. In establishing a protein range, ISDI believes consideration must be given to the nutritional requirements, the lack of UL established for protein, dietary protein intake levels (including population intake distribution as well as average intakes), protein quality and history of apparent safe use, protein content of cow's milk (generally considered as the reference point for follow-up formula for young children and a key ingredient in many formulations) as well as global implications of the recommendations. This is challenging given the diversity of dietary practices and needs across the globe ISDI considers that given all these facts, broader rather than narrow criteria should be reached for protein requirements for follow-up formula for young children.

If this broad protein range is accepted, ISDI proposes that provisions are included in the labelling section of the follow-up formula standard to enable care-givers to differentiate between formula with high protein and formula with low protein. This will enable care-givers to make an informed choice at the time of purchase. One means of doing this could be through the provision of information on NRVs. To achieve this, NRVs for young children need to be established as soon as possible.

Minimum protein requirement

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 have identified that average protein intakes are generally meeting or are above requirements, suggesting that protein intakes are adequate in a majority of young children (12-36 months) (CX/NDSDU 14/36/7).

Based on the totality of the evidence, and in particular new data (e.g. Hörnell 2013; Pimpin 2016,), and while recognizing the debate within the scientific and regulatory community regarding the adequate lower protein level for follow-up formula is ongoing, ISDI recommends to adopt a lower minimum protein level at **1.5g/100kcal** (approximately 6% of energy in the product).

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 are based on maintenance of requirements of 0.66 g/kg bodyweight per day and a protein efficiency utilization 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 compared to previous estimates primarily as a result of changes in the reference body weights 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 young children (12-36 months) calculated from WHO/FAO/UNU protein requirements (WHO/FAO/UNU 2007) using WHO weight-for-age growth standards (WHO 2006) result in an average of 11.3 g protein/day.

For the minimum protein level of follow-up formula for young children, ISDI suggests to establish it based on the updated WHO/FAO/UNU protein requirements for this age group, which equates to approximately 6% of the total protein energy in the product. Considering the approach described previously, and WHO/FAO/UNU protein requirements for infants aged 12 months (1.14g/kg/day), it results in a minimum protein level for follow-up formula for young children of 1.6g/100kcal (based on energy density of 70kcal/100mL). Considering the IOM RDA of 1.05g/kg/day for children aged 1-3 years, this results in a minimum protein content for follow-up formula for young children of **1.5g/100kcal** (IOM 2001).

A similar approach was used by the Early Nutrition Academy (ENA), which recently developed compositional recommendations for follow-up formula for young children aged 12-36 months based on a review on nutritional requirements and dietary intakes for young children worldwide (Suthutvoravut 2015). The expert group proposes that the minimum protein content in the formula products for children aged 12-36 months should be 1.5g/100kcal, which is around 6% of energy (Suthutvoravut 2015).

In addition to establishing nutritionally safe and adequate minimum protein levels for follow-up formula for young children, several national and regional surveys of dietary protein intakes of older infants and young children are to be taken into consideration. The results of these dietary surveys have identified that average protein intakes in many countries are generally above protein requirements for this age group, suggesting that the majority of young children in these countries has adequate protein intakes (CX/NFSDU 14/36/7, Suthutvoravut 2015). With the exception of Bangladesh, studies showed that young children have average protein intakes above the recommended dietary requirements and ranging from around 20g in Philippines, India or China (FNRI 2008, Kapur 2005, Barbarich 2006) to 50g in

Vietnam (Le Nguyen 2013) or even 60g per day in Australia and USA (Webb 2008, Butte 2010) – two to six times higher than the WHO/FAO/UNU safe intake level. In Uganda, data were presented as percentiles and highlighted that even at the 5th percentile, intakes were twice those recommended by WHO/FAO/UNU (Harvey 2010).

Although ISDI acknowledges that no published data showing safety and suitability of a follow-up formula containing 1.5 or 1.6g protein/100kcal specifically in young children are available. Nevertheless ISDI refers to the studies conducted by Ziegler and Inostroza (Ziegler et al (2015), Ziegler (2015b) and Inostroza (2014)) which are randomized clinical trials conducted on infants up to 12 months. They demonstrate adequate growth and development.

When a formula has been assessed in infants as sole source of nutrition and established safe and suitable for this target population, then the formula could be considered safe and suitable for young children in a diversified diet.

In conclusion, based on the available data, in particular recent estimates of protein requirements and considering protein intakes in young children, ISDI requests the 38th session of CCNFSDU to consider adopting a minimum protein level of **1.5g/100kcal, which equates approximately to 6% of energy from protein in the product.**

Maximum level for protein

ISDI considers that, despite no upper safe protein levels have been established by a recognised authoritative scientific body, a maximum level should be proposed to be coherent with other macronutrients.

EFSA (2013) noted Intakes of protein of older infants and young children living in Europe were generally high but not at levels of concern. WHO/FAO/UNU report on dietary protein requirements states that there is no risk to individuals with excessive intakes considerably above the safe intake levels (WHO/FAO/UNU 2007).

In setting a maximum protein level for follow-up formula for young children, the protein content of cow's milk, generally considered as the reference point for follow-up formula for young children and a key ingredient in such products should be taken into account. Consideration should also be given to the diversity of protein intakes across the globe including the protein intakes of young children living in both resource-rich and resource-limited settings. Average protein intakes in a number of resource-rich countries exceed protein requirements, noting however that average intakes do not reflect population intake distribution (Gibney, 2004). Fewer nationally representative data are available from developing countries. While average intakes of young children exceed protein requirements a significant proportion in India, Indonesia, China, and the Philippines still did not meet local RDA's or WHO safe levels despite average intakes meeting requirements (noting comparison to WHO minimum levels was not always available) (FNRI 2008, Nguyen 2013, Poh 2013, Sanjaja 2013). However, in absence of protein intake data, levels of stunting give an indication of the extent of protein-energy malnutrition in a country; stunting is still widespread in many resource-limited countries (WHO 2016).

Milk is recognized as an important part of a healthy diet, including that of young children, with >40 countries recommending its consumption (FAO, 2013). WHO guidelines for non-breast fed children also emphasize the importance of cow's milk consumption in young children as a valuable source of high quality protein (2013 eWG, WHO 2005). The protein content of whole cow's milk is between **3.2 to 3.4g/100 ml** (FAO 2013.This is equivalent to an average protein density of **5.5g/100kcal** [(1)]. The current Codex Standard for follow-up formula has a maximum protein limit which would enable a formula to contain equivalent levels of protein as found in whole cow's milk.

Based on evidence that protein intakes and quality varies globally and that cow's milk is generally considered as the reference point, it is important that protein requirements are not unnecessarily limited. Many children will continue to benefit from products with a higher proportion of energy from protein, particularly high quality protein.

In conclusion, ISDI considers that given all these facts, broader rather than narrow criteria should established for protein requirements for follow-up formula for young children, and a level of **5.5g/100kcal**

(approximately 22% of energy in the product), reflecting the protein density in whole cow's milk, is considered an appropriate maximum.

This is to ensure that products cover different nutritional needs for young children.

(1) *with an average protein density of 5.5g/100kcal (based on an average energy content of 62kcal/100mL and an average protein content of 3.3g/100mL, FAO 2013).*

References

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Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
☐ Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	☐ Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
☒ Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	☐ Alternative value, please specify
Please provide justification for your answer Minimum fat levels may be guided by reduced fat milk (1.5-2% fat, calculated by eWG as 3.5g/100kcal). This will enable formulations targeting the lower level of the energy range to be produced and is consistent with the approach guiding the energy minimum of 45kcal/100mL. ISDI notes younger children are recommended to consume higher fat levels than adults, however from	

age 2 years may choose reduced fat milk options (WHO, 2005). Thus it is appropriate that the minimum should not be lower than reduced fat milk in order to cover the broad age range.

Reference

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

Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?	
☒ Proposed FUF-older infants & cows' milk 6.0 g/100 kcal 1.4 g/100 kJ	☐ Alternative value, please specify

Please provide justification for your answer

ISDI supports retention of the existing maximum of the Codex Standard for Follow-up Formula of 6g/100kcal, providing up to 54% energy from fat in the product. Increased fat levels also support reduced added carbohydrates and properties of the product. The upper range is greater than the EU total diet RI of 35-40% for young children, however as follow-up formula for young children are not meal replacements, and not every food must align to total diet intake distribution, furthermore, other foods may provide reduced fat

Essential Fatty acids

Lipids

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

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

Please provide justification for your answers.

Summary

ISDI supports establishing a minimum for α-linolenic acid of **44mg/100kcal** based on evidence of globally inadequate supply of α-linolenic acid in the diet of young children. It is not necessary to mandate minimum linoleic acid levels, however, if the eWG decides to mandate this nutrient, ISDI then suggests the minimum level in the current Codex STAN 156-1987 of **300mg/100kcal.** Lastly, no maximum or GUL, nor ratio between both linoleic and α-linolenic acid is necessary if a minimum is established for both linoleic acid and α-linolenic acid.

Rationale – Scientific justification

Fat is an important dense source of energy, it facilitates the absorption of fat-soluble dietary components such as vitamins and supplies essential fatty acids (α-linolenic acid (ALA) and linoleic acid (LA)) to the body.

ISDI recommends to add α-linolenic acid to the list of mandatory composition criteria as the eWG Chair in 2014 highlighted evidence of globally inadequate supply of ALA in the diet of young children. EFSA (2013) also outlined intake data of fatty acids was scarce in the EU, and of the data available, that dietary intakes of α-linolenic acid in young children were low relative to the Adequate Intake.
Minimum levels could be defined based on minimum FAO AI for 6-24 months i.e. 0.4% of total energy

from ALA, which could be applied to the whole product 44mg/100kcal (i.e. 0.4% of 100kcal = 100*0.004/9). Establishing levels for LA and ALA should be based on expert recommendations defined for n-3 and n-6 fatty acids.

Linoleic acid intake is globally adequate as an essential fatty acid. ISDI considers that it is not necessary to mandate minimum LA levels on the basis that this would not meet the key overarching principles outlined by the eWG:

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

However, if the eWG decides to mandate this nutrient, ISDI then can support the minimum level is of the current Codex STAN 156-1987 of **300mg/100kcal.**

Finally, ISDI is also of the position that if a minimum level is established for both ALA and LA, then a ratio is not required. FAO (2010) concluded there was insufficient evidence to set a ratio of α-linolenic acid:linoleic acid in the diet:

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

If a minimum is not established for either LA or ALA, then consideration should be given to the establishment of a ratio.

Phospholipids are naturally present in milk. ISDI therefore considers that there is no necessity to establish a minimum level for phospholipids in follow-up formula for young children.

References

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Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?	
☐ Yes Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG? ☐ Yes ☐ No ☐ Alternative, please specify and provide	☒ No If a minimum is not established for both linoleic acid and α-linolenic acid, a ratio could be considered.

justification for your answer.	
Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?	
☐ Yes Should this level be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk? ☐ Yes ☐ No ☐ Alternative, please specify and provide justification for your answer.	☒ No
Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
☐ Yes Please state what the maximum level should be, and provide justification for your answer. ISDI is of the opinion that further consideration is needed regarding the appropriateness of setting a maximum TFA as a percentage of total fat, when all sources of industrial TFA in these products will be limited through restriction of hydrogenated vegetable oils. The fat level in cow's milk has to be taken into account to allow use of milk fat at a certain level in follow-up formula for young children As discussions are still ongoing, ISDI reserves the right to further consider of this element before the 38th CCNFSDU meeting.	☐ No

Rationale – Scientific justification:

Current recommendations by the WHO/FAO from 2008 state trans-fatty acids (TFAs) should be below 1% of total energy intake. The evidence for the association of these fatty acids with major health and disease outcomes was graded as "convincing" WHO, 2010. EFSA established DRVs on all the fatty acids in 2010 as well and their recommendation for TFA intake is to keep 'as low as possible'. The ENA recommends keeping trans-fatty acids below 2% of total fat, because of the potential adverse effects.

Nevertheless, regulators, public health bodies and WHO/ FAO are still working to reduce the detrimental effects of TFA in the diet by trying to limit/ban industrial TFA, but not intakes of ruminant TFA which are naturally inherent in the milk (EC, 2015; FAO,2010; UAUY, 2009).

Inclusion of a clause banning the use of hydrogenated vegetable oils in follow-up formula for young

children could effectively eliminate industrial TFA from these products.

A recent systematic review and meta-analysis commissioned by the World Health Organisation (de Souza et al., 2015) reported that industrial, but not ruminant, trans fats were associated with coronary heart disease (CHD) mortality (1.18 (1.04-1.33) vs 1.01 (0.71-1.43 for ruminant)), and CHD (1.42 (1.05-1.92) vs 0.93 (0.73-1.18)). Ruminant trans-palmitoleic acid was associated positively (protective) with type-2 diabetes (0.58 (0.46-0.74)).

Recently, FAO acknowledged that the quantity of TFA consumed may also be a factor in the disease risk. Present knowledge on TFA intakes in most countries is not robust (FAO 2013).

The quantities of ruminant TFA (rTFA) consumed are low in most of the populations studied (generally <1.0 percent E). Thus, even when total ruminant fat intake is relatively high, the potential amount of TFA from this source is still quite modest. These data do not discount the possibility that much higher amounts of ruminant fat could have adverse effects, but in the amounts consumed in actual diets rTFA do not appear to be major contributors to CHD risk (FAO 2013). It is also noted that, at amounts currently consumed, rTFA do not have detectable adverse relationships with disease risk but further investigation is warranted. At the present time, both sources of TFAs, and especially specific TFA isomers, should be considered when assessing effects on disease risk (Mozaffarian, Aro and Willett, 2009, cited in FAO 2013).

Regarding the inherent levels of ruminant TFA in milk: the eWG summarised data that suggested whole milk and skim milk TFA levels range from 0.1- 6.5% TFA in the milkfat. However, data averages from analysis of milkfat and whole milk do not support this low minimum value. Milk data from over 14 European countries shows average TFA levels as a proportion of total fat in milk are significantly higher ranging from 3.19-5.09% (Aro, 1998), with data from British supermarkets also showing average levels of 3.78-5.46% (Kliem et al, 2013). Analysis of milkfat by Precht and Molkentin (2000) also supported average data from some countries around 4-5.5%.

References

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de Souza RJ, Mente A, Maroleanu A *et al* (2015) Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. *British Medical Journal*, 351:h3978

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FAO (2013) Milk and dairy products in human nutrition.

Hafekost *et al.* (2014) Systematic Review of the evidence for a relationship between trans-fatty acids and blood cholesterol prepared on behalf of Food Standards Australia New Zealand.

Kliem *et al.* (2013) Seasonal variation in the fatty acid composition of milk available at retail in the United Kingdom and implications for dietary intake. *Food Chemistry,* 141, 274–281

Precht D, Molkentin J (2000) Trans unsaturated fatty acids in bovine milk fat and dairy products. *Eur. J.*

Lipid Sci. Technol, 102, 635-639 Uauy *et al.* (2009) Review: WHO Scientific Update on trans fatty acids: summary and conclusions. *EJCN,* 63, 568-75.
Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (*Commercially hydrogenated oils and fats shall not be used in follow-up formula*) also apply to follow-up formula for young children?
Please provide justification for your answer. Yes, ISDI considers that footnote 7 should apply to follow-up formula for young children based on the rationale outlined above.

Carbohydrates

Total Available Carbohydrates	
Is a minimum available carbohydrate level required, if a consensus is reached on establishing minimum and maximum levels for energy, protein and total fat?	
☐ Yes	☒ No
Please provide your rationale: Currently, ISDI does not support a minimum carbohydrate level, as to be consistent with the provisions in section 3.2.3 of the current Codex follow-up formula standard. ISDI however reserves the right to further consider this point and elaborate more for the 38th CCNFSDU.	
If you support establishing a minimum available carbohydrates level, what level do you support?	
☐ Full fat cows' milk 7.5 mg/100 kcal 1.8 mg/100 kJ	☐ IEG 2015 and proposed Codex FUF-OI 9.0 g/100 kcal 2.2 g/100 kJ
Please provide your rationale: Not applicable. ISDI do not support a minimum on basis this is not necessary as this will be naturally occurring from the raw ingredients, and energy limits, fat and protein will naturally drive minimum levels of carbohydrate. ISDI notes carbohydrates are expressed in g/100kcal (and not in mg/100kcal)	
If limits are established for sugars, is there a need to also set a maximum/GUL for total available carbohydrates?	
☒ Yes	☐ No
Please provide your rationale: ISDI supports the establishment of a maximum total available carbohydrate level. The establishment of maximum level requires further consideration after the minimum protein and fat levels are defined.	
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?	

☒ Yes, a maximum level should be established	☐ Yes, a GUL level should be established

Please provide your rationale:

ISDI's position is that a maximum level should be established to limit total available carbohydrates, but that this should not be established until the protein and fat levels are defined.

It is suggested that a cap to total carbohydrates is set to restrict addition of refined carbohydrates/ added sugars. This cap will be dependent on minimum protein and fat levels once defined.

If you support establishing a maximum/GUL, do you support 14 g/100 kcal (3.3 g/100 kJ)?

☐ Yes	☐ No (please specify your alternative).

Please provide your rationale:

Summary

ISDI supports establishing a maximum for total carbohydrates; however, this limit should only be established after minimum protein and fat levels are defined. Whilst, ISDI could potentially support a maximum level of 14g/100kcal, this cannot be confirmed at this time as it depends on other agreed macronutrient limits.

Rationale

Predominantly, carbohydrate ingredients in follow-up formula for young children may include lactose from milk ingredients, plus other added sugars and carbohydrate ingredients. Carbohydrates are an important energy source for the body and are a necessary part of the diet; however, excessive intakes can pose issues for health. Therefore, ISDI considers it prudent to set a maximum level for total available carbohydrate. This maximum level cannot be established until protein and fat levels have been established and ingredient combinations have been considered. Whilst, ISDI could potentially support a maximum level of 14g/100kcal, this cannot be confirmed at this time**.**

Carbohydrates footnote

Free sugars

While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.

☐ Proposed Codex FUF-OI Standard Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.	☐ IEG 2015 Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	☒ An alternative level (please specify) Sucrose and fructose should be ≤10% of total energy.

Please provide your rationale:

The WHO strongly recommends a reduced intake of free sugars throughout the life course in both adults and children below 10% of total energy intake. Reasons to limit sugar intake are the positive associations between free sugars and body weight, as free sugars contribute to the overall energy density of diets, and may promote a positive skewed energy balance. There is increasing concern that intake of free sugars increases overall energy intake and may reduce the intake of foods containing more nutritionally adequate calories. This could result in an unhealthy diet, increasing the risk of non-communicable diseases (NCDs)

in later life (WHO 2015).

Pure or refined lactose should be excluded, given that it can be used without a maximum limit as it is not used for sweetening purposes but rather to manage the gross composition of products within the limits applied for macronutrients. In addition, in order to be more precise in the standard, ISDI proposes to consider limiting specifically sucrose and fructose with a maximum limit of 10% of total energy.

Reference

WHO (2015) Guideline: Sugars intake for adults and children. World Health Organization.

Lactose

☐ Proposed Codex FUF-OI Standard and Codex IF Standard Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.	☐ IEG 2015 The main source of carbohydrates should be lactose, which should provide not less than 50% of total carbohydrates, equivalent to 4.5 g/100 kcal.

Please provide your rationale:

Lactose is one of the main sources of carbohydrates within follow-up formula for young children, therefore if there is a cap on total carbohydrates amounts, this will automatically cap total lactose levels. As such there is no need to define a level here.

The use of glucose polymers (maltodextrin) should be maintained in the standard for follow-up formula for young children.

ISDI considers lactose should be the preferred source of carbohydrates within follow-up formula for young children given it is naturally present and abundant in mammalian milk, including the core ingredients used in follow-up formula for young children.

Other permitted carbohydrates

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

Please provide your rationale:

In principle, ISDI can agree with the IEG 2015 proposal on the list of permitted carbohydrates. Nevertheless, ISDI considers that there is no need for the inclusion of a positive list of other permitted carbohydrates. This level is of prescription is not warranted for this product category.

Iron

Iron

While a consensus was reached on the minimum compositional requirements for iron in follow-up formula for young children, there were differing opinions on a maximum or GUL.

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.0	[2.0]	[3.0]
mg/100 kJ	[0.25]	[0.3]	[0.7]

Should a maximum level or GUL be established for iron?

☐ Yes, a maximum level should be established ☒ Yes, a GUL level should be established	☐ No

Please provide your rationale:

Summary:
ISDI supports a GUL for the mandatory iron addition to follow-up formula for young children (12-36 months).

Rationale – Scientific substantiation:

A low dietary intake of iron has been reported in a number of countries as outlined in this consultation paper. If performing a supplemental role in the diets of young children, follow-up formula for young children would require higher levels of iron than that found in cow's milk.

On average, cow's milk and milk-based product contain very low levels of iron (< 0.1 mg/100kcal) (EFSA, 2013) and the potential for iron deficiency is considerable if cow's milk or milk-based products are the main protein sources of the young child diet when comparing to the WHO recommended nutrient intakes for iron (5.8 mg/day).

A broader range for iron in follow-up formula for young children is also more suitable for this age group, compared with the range proposed for follow-up formula for older infants, to accommodate the gaps in dietary intake in countries with various and increasing diversified diets.

The option for a GUL, as opposed to a maximum level, is scientifically supported by the 2015 IEG who proposed compositional requirements for follow-up formula for young children based on nutritional requirements and safety. There is no evidence that the GUL for iron would be unsafe.

Reference

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408, 103 pp. doi:10.2903/j.efsa.2013.3408

If you support establishing a maximum or GUL, please select your preferred value, providing scientific rationale to support your preferred choice.

☐ Maximum (Proposed Codex FUF-OI) 2.0 mg/100 kcal 0.5 mg/100 kJ	☒ GUL (IEG 2015) 3.0 mg/100 kcal 0.7 mg/100 kJ
☐ Alternative value (please provide level (max/GUL))	

Please provide your rationale:

Summary:
ISDI supports a GUL of 3.0 mg/100kcal for the mandatory iron addition to follow-up formula for young children (12-36 months).

Rationale – Scientific substantiation:
ISDI considers a GUL of 3.0 mg/100kcal adequately meets the safety limits for iron in young children receiving follow-up formula for young children products as part of their total dietary intake on the basis of:

- The GUL should ensure that the UL is not exceeded if follow-up formula for young children is used. The IOM provides an upper limit of 40 mg/day for children aged 1-3 years old. When targeting 50% of the UL iron = 20mg/day & if fed one 300mL serve / day and at an energy range of 45-70kcal/100mL, the child could receive between 9.52 – 14.81mg iron per day
- ISDI acknowledges this is a particularly high level of iron intake, despite well within the IOM upper limits
- ISDI proposes the approach to multiply the agreed minimum iron level for follow-up formula for young children (1mg/100kcal) by 3-5 times (based on ENA paper) which results in 3-5mg/100kcal.

ISDI supports the precautionary approach and the proposal of a GUL of 3.0 mg/100kcal.

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?	
☒ Yes	☐ No

Please provide your rationale:

ISDI supports a separate minimum and maximum/GUL for soy protein isolate formulae due to the potentially lower absorption efficiency. This approach is consistent with the separate levels for soy protein isolate formulae in follow-up formula for older infants.

If you support establishing separate minimum and maximum/GUL levels for soy protein isolate formulae, should it be the same as the proposed Codex Standard for Follow-up Formula for older infants (a minimum of 1.5 mg/100 kcal (0.36 mg/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ)?	
☐ Yes	☒ No (please provide alternative values, with justification for your response)

Please provide your rationale:

ISDI supports the same minimum iron level of 1.5 mg/100kcal as follow-up formula for older infants and a GUL of 3.5 mg iron/100kcal

Rationale – Scientific substantiation:
The primary reason for establishing separate levels for soy protein isolate formulae is due to the potentially lower absorption efficiency.

For follow-up formula for older infants, the minimum and maximum levels for soy protein isolate formulae are 0.5mg/100kcal higher than the values for milk based formulae to compensate for a potential lower absorption efficiency of iron. As the levels supported for cow's milk based formulas are a minimum of 1.0mg/100kcal and a GUL of 3.0mg/100kcal, this would correspond to a :

- Minimum of 1.5mg/100kcal
- GUL of 3.5mg/100kcal

Calcium

Calcium
No consensus was reached on the requirements for calcium in follow-up formula for young children. Noting that full fat cows' milk contributes 190 mg calcium/100 kcal (range 184 - 201 mg/100 kcal) and the average amount of calcium in reduced fat cows' milk is 259 mg/100 kcal (range 240 – 280 mg/100 kcal), Please provide comment on the below options:

Calcium **Unit** mg/100 kcal mg/100 kJ	**Minimum** [50] [90] [200] [18] [22] [24] [48]	**Maximum** [N.S.]	**GUL** [180] [NS] [43]
Minimum:			
☒ Current Codex FUF standard 90 mg/100 kcal 22 mg/100 kJ		☐ Proposed Codex FUF standard for older infants 50 mg/100 kcal 12 mg/100 kJ	
☐ IEG 2015 200 mg/100 kcal		☐ Alternative value, please specify	

Please provide justification for your answers.

ISDI considers calcium to be an important nutrient to mandate as milk is a key source of this nutrient in the diet.

ISDI notes the FAO (2013) minimum and maximum calcium density is 147-194mg/100kcal (when values per 100g are converted using the average energy density of whole milk at 62kcal/100g). The minimum and maximum (FAO, 2013) calcium levels in whole milk translate to approximately 55-72% of the NRV for calcium.

As calcium and protein levels are linked, and technical feasibility issues may be encountered when formulating higher calcium levels in low protein products, ISDI will then confirm a final preference for calcium minimum after protein levels are defined.

Of the three options presented by the eWG, ISDI currently prefers 90mg/100kcal and note this is approximately half the average protein density of whole milk.

References

FAO (2013) *Milk and dairy products in human nutrition.* Rome: Food and Agriculture Organization.

Maximum/GUL:	
☐ Current Codex FUF standard Maximum: N.S.	☐ Proposed Codex FUF standard for older infants GUL: 180 mg/100 kcal GUL: 43 mg/ 100 kJ
☐ IEG 2015 GUL: N.S.	☒ Alternative value, please specify

ISDI supports a GUL for Calcium noting the absence of maximum or GUL defined in the current Standard and the low risk of fortification approaching the upper limit for calcium (IOM, 2001 2500mg/day). The level for GUL would need to be determined until the protein levels are established due to the calcium protein interaction/relationship.

Reference

Food and Nutrition Board, Institute of Medicine, National Academies (IOM) (2001) Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Vitamins
http://www.nationalacademies.org/hmd/Activities/Nutrition/SummaryDRIs/~/media/Files/Activity%20Files/Nutrition/DRIs/ULs%20for%20Vitamins%20and%20Elements.pdf

Calcium
Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included? Ratio calcium/phosphorus

Min	Max
1:1	2:1

☐ Yes	☐ No

Please provide your rationale:

ISDI is of the opinion that further consideration is needed on the calcium-to-phosphorous ratio once the minimum and GUL levels for calcium are defined. To our knowledge, there are no deficiencies of phosphorus in the diet of young children. Moreover, given the diversified diet of young children, a ratio for Ca/P might not be necessary as the diet contains other possible sources of phosphorus.

Vitamin A

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

Unit	Minimum	Maximum	GUL
µg RE/100 kcal	[75] [60] [50]	[225] [180]	[200] [180]
µg RE/100 kJ	[18] [14] [12]	[54] [43]	[48] [43]

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

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

Minimum

☐ Current Codex FUF Std & proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	☒ IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	☐ WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ

Please provide your rationale:

ISDI supports the mandatory addition of vitamin A to follow-up formula for young children at a minimum level of 60 µg RE/100 kcal.

30% of the NRV for vitamin A equates to 40ug/100mL. This translates to 57-89ug/100kcal when using the energy range of 45-70kcal/100mL. ISDI thus took the lowest figure of 57ug/100mL and suggests this level guides the minimum. This is 'close' to the ENA proposal of 60ug/100kcal and ISDI also supports this level.

Maximum

☒ Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	☐ Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ

Please provide your rationale:

ISDI supports the mandatory addition of vitamin A to follow-up formula for young children at a maximum level of 225 µg RE/100 kcal.

Rationale

ISDI considers a maximum of 225 mcg/100kcal is acceptable for follow-up formula for young children on the basis of:

- A maximum is more appropriate than a GUL due to the potential toxicity of vitamin A.
- The IOM provides an upper limit of 600 mcg/day vitamin A for children aged 1-3 years old. Targeting 50% of the UL vitamin A = 300 mcg/day. If this is provided in 300mL/ day and at an energy range of 45-70kcal/100mL, the child could receive between 142.9 – 222.2 mcg Vitamin A per day.
- Further support for this level is provided when taking the approach to multiply the Follow-up Formula for Young Children minimum level of vitamin A (0.6mg/100kcal) by 3-5 times, providing 180 – 300 mcg/100kcal. The level of 225 mcg/100kcal is within this range.
- The current Codex Standard for Follow-up Formula provides a maximum vitamin A level of 225 mcg (RE) /100kcal and this is similar to the maximum of 200ug/100kcal recommended by ISDI for Follow-up Formula for Older Infants (ISDI 2016)

For these reasons, ISDI supports a vitamin A maximum of 225 mcg (RE) /100kcal for follow-up formula for young children.

Reference

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.

GUL	
☐ WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ	☐ IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ
Please provide your rationale: Not applicable.	
Do you support the footnote below, agreed to by the Committee for follow-up formula for older infants (REP16/NFSDUE Appendix III)? [x] expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.	
☒ Yes	☐ No

Vitamin D

Vitamin D	
Do you support that mandatory addition of vitamin D to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: ISDI supports the mandatory addition of vitamin D to follow-up formula for young children at a minimum level of 1.5µg/100kcal as proposed by ENA. Vitamin D insufficiency in young children is frequently	

documented, even in some lower latitude countries.

Rationale - Justification

Following the ISDI approach, covering 30% of NRV (using a 300mL serve), is deemed an appropriate target for a minimum level. At an energy density of 70kcal/100mL this translates to 1.43ug/100kcal, which is comparable to that suggested by ENA.

Please state whether vitamin D should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.

Answer:

ISDI considers a maximum of 4.5 mcg/100kcal is acceptable for follow-up formula for young children on the basis of:

- The maximum should ensure a safe limit and the UL should not be exceeded if follow-up formula for young children is used. The IOM provides an upper limit of 63 mg/day vitamin D for children aged 1-3 years old. When targeting 50% of the UL vitamin D = 31.5 mcg/day & if fed one 300mL serve / day and at an energy range of 45-70kcal/100mL, the child could receive between 15 – 23mcg vitamin D per day
- ISDI acknowledges this is a particularly high level of vitamin D intake, despite well within the IOM upper limits
- ISDI proposes the approach to multiply the proposed minimum vitamin D level (1.43mcg/100kcal) for follow-up formula for young children by 3-5 times (based on ENA paper) which results in 4.29 – 7.15mcg/100kcal.
- ISDI considers the level of 7.1mcg/100kcal vitamin D is close to the NRV of 10ug/100kcal and the contribution of the nutrient through follow-up formula for young children should be considered in context of total dietary intake of vitamin D

Therefore, ISDI supports a maximum of 4.5mcg/100kcal (3x the minimum) for follow-up formula for young children which in this case, is also in line with ENA recommendation

Zinc

Zinc	
Do you support that mandatory addition of zinc to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: ISDI supports the mandatory addition of zinc at a minimum level of 0.6 mg/100kcal**.** If 30% of the NRV is targeted (approx. 0.41mg/100mL), this is equivalent to 0.6-0.91mg/100kcal at 70 and 45kcal/respectively. The lowest value of 0.6mg is selected.	
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: ISDI supports having a GUL for zinc of 1.8 mg/100kcal on the basis this is approx. 3 times the minimum	

level and 50% of the UL with the lowest energy density.

Rationale – Scientific justification

ISDI notes there is no maximum or GUL specified in the current Codex Follow-up formula standard. A GUL should be set as there may be inherent variability in the zinc level of some raw materials used in product manufacture (e.g. dairy commodities, carbohydrates from vegetable sources etc.). This may be due to seasonal variability and geographical location (i.e. region of the world where the ingredients are sourced). It is important that the range for zinc takes this into account to ensure that young children (12-36 months) receive the recommended intake.

ISDI considers a 1.8 mg/100kcal GUL is acceptable for follow-up formula for young children on the basis of:

- The GUL should ensure the UL is not exceeded if follow-up formula for young children is used. The IOM provides an upper limit of 7 mg/day zinc for children aged 1-3 years old. When targeting 50% of the UL for zinc = 3.5 mg/day and if fed one 300mL serve / day and at an energy range of 45-70kcal/100mL, the child could receive between 1.67-2.59 mg zinc per day
- Further support for this level is provided when taking the approach to multiply the follow-up formula for young children minimum level (0.6mg/100kcal) by 3-5 times, this also results in a similar range 1.8-3 mg/100kcal.

Therefore, with no current GUL specified in the Codex Standard for Follow-up Formula and based on the scientific approach described above, ISDI supports a GUL of 1.8 mcg/100kcal for follow-up formula for young children.

Vitamin C

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

Answer:

ISDI supports the mandatory addition of vitamin C to follow-up formula for young children mainly due to its role in aiding iron absorption. A minimum level of **4.5mg/100kcal** as suggested by ENA, and which corresponds to 20 -30% of the FAO/WHO NRV (at 45-70kcal/100mL & a 300mL serving) seems to be appropriate.

Rationale – Scientific justification

Vitamin C plays an important role in the body, e.g. it is an enzyme cofactor for numerous biochemical reactions; it is essential for the biosynthesis of collagen and it is involved in the metabolism of cholesterol to bile acids (EFSA, 2014). It is also essential for iron absorption (Halberg et al., 1989). There are numerous reports in the literature of low or inadequate vitamin C intake among young children (Suthutvoravut *et al.*, 2015). The WHO has recommended that the daily average intake of vitamin C for young children (1-3 years) is 30mg/day.

References

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

Halberg L, Brune M, Rossander L (1989) The role of vitamin C in iron absorption. *Int J Vitam Nutr Res Suppl,* 30:103-8.

Suthutvoravut U, Abiodun P, Chomtho S, Chongviriyaphan N, Cruchet S, Davies P, Fuchs G, Gopalan S, van Goudoever J, delaReyNel E *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. *Ann Nutr Metab,* 67:119-132.

Please state whether vitamin C should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.

Answer:

Summary

ISDI can support a GUL for vitamin C noting the non-specified maximum in the current Standard and the low risk of fortification for vitamin C. The level for GUL would need to be determined once the protein levels are defined.

ISDI notes the technical challenges associated with vitamin C and thus if a GUL is to be specified, a broad range is necessary. In considering a GUL, ISDI further notes the applicability of the GUL defined in the standard for follow-up formula for older infants of 70mg/100kcal.

Rationale – Scientific justification

Vitamin C is one of the most challenging nutrients for the young child formula manufacturers due to a multitude of factors including its stability, analytical variability, etc. Vitamin C degrades rapidly in water when exposed to air. Loss over shelf life is considerably greater in liquids than in powders and depends on product form and package type. Powder products are generally packed under nitrogen and the available oxygen that remains in the powder after packaging quickly drops during the first week (to almost zero). Liquid products generally do not have this stability after the first week and, depending on package and shelf life, losses are typically 30–50% but may be as high as 75% (MacLean et al., 2010).

It is important that the range for vitamin C takes into account factors relating to the product, shelf-life and packaging to ensure that young children (12-36 months) receive the recommended intake.

Reference

MacLean WC, Van Dael P, Clemens R, Davies, J, Underwood E, O'Risky L, Rooney, D; Schrijver J. (2010) Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. *Journal of Food Composition and Analysis,* 23:44–53

Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: ISDI proposes that B12 is mandated for follow-up formula for young children on the basis this is an	

essential nutrient for which cow's milk is a key contributor to a young child's dietary intakes, particularly for children who consume little other animal products. Minimum levels of vitamin B12 in whole milk (0.25ug/100g i.e. 0.40ug/100kcal when converted using the average energy density of whole milk at 62kcal/100g, FAO, 2013) contribute a 83% of the vitamin B12 NRV (0.9ug/day) per 300mL serve, with average levels in whole milk (0.51ug/100g i.e. 0.82ug/100kcal) contributing 170% of the NRV per 300mL serve. Similar to the approach taken for other nutrients, ISDI proposes 30% of the NRV is targeted per 300mL serve i.e. 0.13ug/100kcal when converted at the maximum energy density of 70kcal/100mL (or rounded up to ENA proposal of 0.15ug/100kcal).
Please state whether vitamin B12 should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.
Answer: ISDI can support a GUL for Vitamin B12 noting the non-specified maximum in the current Standard and the low risk of fortification for vitamin B12. The level for GUL would need to be determined once the protein levels are defined. Furthermore, this level would also need to take into account both variable B12 levels in the milk ingredients as well as shelf life losses of up to 55% (Maclean et al, 2010). *Reference* MacLean WC, Van Dael P, Clemens R, Davies, J, Underwood E, O'Risky L, Rooney, D; Schrijver J. (2010) Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. *Journal of Food Composition and Analysis,* 23:44–53

Riboflavin

Riboflavin	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: ISDI proposes that riboflavin is mandated in follow-up formula for young children on the basis this is an essential nutrient for which cow's milk is a key contributor to a young child's dietary intakes. Similar to the approach taken with other nutrients, ISDI propose that 30% of the NRV (0.5mg/day) per 300mL is targeted for minimum levels, resulting in 0.07mg/100kcal, which rounds up to the current Codex Follow-up Formula Standard. ISDI notes this minimum is less than the minimum levels of riboflavin in whole cow's milk (0.17mg/100g i.e. 0.27mg/100kcal when converted using the average energy density of whole milk at 62kcal/100g, FAO, 2013) which contribute a 102% of the NRV (0.5mg/day) contributing 120% per 300mL serve. *Reference* FAO. (2013) *Milk and dairy products in human nutrition.* Rome: Food and Agriculture Organization.	

Please state whether riboflavin should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.
Answer: ISDI can support a GUL for Riboflavin noting the non-specified maximum in the current standard and the low risk of fortification for Riboflavin. The level for GUL would need to be determined once the protein levels are defined and would need to take into account the inherent variability of riboflavin levels from lactose and milk protein ingredients as well as the high level of degradation for this nutrient >60% across shelf life (Maclean et al, 2010). Furthermore, this level could be determined only once the protein levels are defined. *Reference* MacLean WC, Van Dael P, Clemens R, Davies, J, Underwood E, O'Risky L, Rooney, D; Schrijver J. (2010) Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. *Journal of Food Composition and Analysis,* 23:44–53

Sodium

Sodium	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
☒ Yes	☐ No
Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.	
Answer: Not specified	
Please state whether sodium should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: ISDI recommends setting a **maximum level** for sodium of no more than 85mg/100Kcal for sodium. Considering that follow-up formula for young children should provide 15% of the daily energy intake, and taking 1000mg as the upper limit (IOM 2001), we can consider that staying with a maximum of 85 mg/100 kCal could by appropriate. **Rationale – Scientific justification** Sodium is an essential nutrient that must be provided by the diet mainly through salts and in particular sodium chlorate. Sodium is required by the body for several important biological functions, such as regulation of blood volume, blood pressure, and acid/base balance in the body. Although data of young children are limited, population studies report the relationship between high sodium intake and high blood pressure (Aburto 2013). Some studies suggest a relation between early dietary experience and liking for the taste of salt, both in infants and at preschool age. If such a preference for an increased salt intake persists throughout life, this may eventually increase the risk of hypertension (Stein 2012). Dietary Recommendation on salt intake already exist : IOM recommendation: AI is 0.37 g/d for 7-12m infant, 1 g/d for 1-3y toddler. UL is 1.5g/d for 1-3y toddler.	

WHO recommends a reduction to <2 g/day sodium (5 g/day salt) in adults. WHO recommends a reduction in sodium intake to control blood pressure in children (2-15y). The recommended maximum level of intake of 2 g/day sodium in adults should be adjusted downward based on the energy requirements of children relative to those of adults. The recommendation for children does not address the recommended period of exclusive breastfeeding (0–6 months) or the period of complementary feeding with continued breastfeeding (6–24 months).

EFSA considers that a sodium intake of 170 to 370 mg/d is adequate for the majority of young children (12 to < 36 months) (EFSA 2013).

CODEX Standards:
Current Follow-up formula Standard is 20-85mg/100kcal.

Reference

Aburto N J, Ziolkovska A, Hooper L, Elliott P, Cappuccio F P and Meerpohl JJ (2013) Effect of lower sodium intake on health: systematic review and meta-analyses. *BMJ,* 346:f1326

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

Food and Nutrition Board, Institute of Medicine, National Academies (IOM) (2001) Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Vitamins
http://www.nationalacademies.org/hmd/Activities/Nutrition/SummaryDRIs/~/media/Files/Activity%20Files/Nutrition/DRIs/ULs%20for%20Vitamins%20and%20Elements.pdf

Stein LJ, Cowart BJ, Beauchamp GK (2012) The development of salty taste acceptance is related to dietary experience in human infants: a prospective study. *Am J Clin Nutr,* 95(1):123-9

SCOPE & LABELLING

Scope & Labelling When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.
Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?
Please provide justification for your answer. ISDI favours a standard which comprises two parts corresponding to composition criteria and other specific labelling criteria for older infants (part A) and young children (part B). Some labelling provisions are indeed common for both parts. Therefore the current structure in section 9 of Codex Standard 156-1987 should be retained. These provisions are as follows: **9.Labelling Introduction Section** The requirements with respect to the appropriate languages can be included as well (as is currently

stated in Codex STAN 72-1981. Further reference to Codex STAN 1-1985 (General Standard for Labelling of Prepackaged foods).

9.1 The Name of the Food (section 9.1.2, 9.1.3, 9.1.4) with a few changes as outlined in the section below.
9.2 List of Ingredients
9.3 Declaration of Nutrition Value
9.4 Date Marking and Storage Instructions
9.5 Information for Utilization with few changes as outlined in the section below
9.6 Additional Requirements

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

Please provide justification for your answer.

Although it should be part of the common prescription as outlined above, paragraph 9.1 should be modified as to cover the proposed parts for older infants (part A) and young children (part B).

9.1 The Name of the Food to be replaced by
9.1.1 The name of the food shall be "follow-up formula for older infants" and “follow-up formula for young children”. In addition thereto, any appropriate designation may be used in accordance with national usage.
9.1.2 Those products which are prepared from whole or skimmed milk in accordance with section 3.3.1.2 (XXXX to be adapted) and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula for older infants based on milk" and “follow-up formula for young children based on milk”
9.1.3 All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight.
9.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase

Rationale – Justification
Consideration should be given to a naming convention that accurately reflects the compositional differences outlined with the Follow-up Formula standard for Older Infants and Young Children. ISDI recommends the use of the terms “Follow-up Formula for Older Infants” and “Follow-up Formula for Young Children”. This is necessary to reflect the different age groups for which each Follow-up Formula product is intended and to ensure appropriate use.

Particularly, Follow-Up Formula adapted for Young Children as part of the supplementary diet offered at the market place would contribute to the health status of young children, and help to address

- excessive nutrient supply through non-adapted “general food” (e.g. excess of protein and some micronutrients in so called “fortified milks”);
- nutrient deficiencies compared to inadequate “general food” (e.g. lack of essential nutrients in cow’s milk);
- safety concerns, as adequate safety criteria are specifically developed for this age group

9.5 Information for Utilization
9.5.2 The labelling of a Follow-up Formula for Older Infants shall include a statement that Follow-up Formula for Older Infants is recommended as of 6 months of life.
The labelling of a Follow-up Formula for Young Children shall include a statement that Follow-up Formula for Young Children is recommended as of the 12 months of life.

ISDI further considers that CAC/RCP 66-2008 (Code of Hygienic Practice for Powdered Formulae for Infants and Young Children) should be applicable. This Code covers follow-up formula from 6 months of age and including for young children.

9.6 Additional Requirements
Section to be maintained.

Justification
See below.

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

Answer:

With respect to section 9.5.2 (utilization) and to enable informed choice, parents and care givers should be able to obtain sufficient information from manufacturers about the best age of introduction of both types of formulae.

Consequently, additional labelling provisions for Follow-Up Formula for older infants aligned with the EU (Directive 2006/141/EC superseded by Delegated Regulation (EU) 2016/127), should be introduced e.g. “a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infants specific growth and development needs.”
(Directive 2006/141/EC)

An additional provision should also be introduced for follow-up formula for young children for the age of introduction (i.e. from 12 months on).

The scope should be amended to read as follows:

“This standard applies to the composition and labelling of Follow-up Formula for Older Infants and of Follow-up Formula for Young Children”

The subsequent statement “It does not apply to foods covered by the Codex Standard for Infant Formula (CODEX STAN 72-1981).” does not require amendment.

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

Answer:

ISDI is of the opinion that no specific reference to WHA resolutions should be made in the revised Codex Standard for Follow-up Formula.

ISDI is particularly concerned at the prospect of extending some of the restrictions applied to infant formula being applied to follow-up formula. As stated above, follow-up formula is a part of a diet of an older infant and/or young child and it is not suitable to satisfy, by itself, the nutritional requirements of normal healthy infants or young children.

The principles of Codex are protecting the health of consumers and facilitating international food trade. Therefore, other factors/aspects/elements such as governmental policies, practices and external body recommendations should not be included in a Codex Standard. ISDI is of the opinion that no specific reference to WHA resolutions should be made in the revised Codex Standard for Follow-up Formula.

At very rare occasions reference to WHO texts and a resolution are included on purpose. This is particularly the case with the Code of Marketing of Breast-milk Substitutes (1981) (the Code) in Codex STAN 72-1981. It is worth noting that Codex STAN 72-1981 does not reference the associated WHA resolution, WHA34.22 (the resolution made at the time the Code of Marketing was finalised).

It is not appropriate that product standards deviate in their scope into areas of public health policy or statements on nutritional policy. Policy statements relating to health are beyond the scope of the Codex Alimentarius. ISDI questions the legitimate basis to include those statements based on the Codex rules of procedures.

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

Answer:

The Codex standards setting system, as defined in the Rules of Procedures, is evidence based and technically focused. Even though technical aspects could be considered, it deliberately maintains a separation with policy and activities undertaken by international organisations (WHO, FAO, UNESCO, UNICEF, WTO). WTO recognised Codex Alimentarius as a standard setting body and even as a reference for dispute resolutions.

Resolution WHA69.9 requests the Director General of WHO "to strengthen international cooperation with relevant United Nations funds, programmes and specialized agencies and other international organizations, in **promoting national action** [our underline] to end the inappropriate promotion of foods for infants and young children, taking into consideration the WHO guidance recommendations".

If the Resolution WHA69.9 states that Member States recognize the role of Codex in defining standards on the composition, safety and labelling of products, ISDI's position is that Codex must maintain a focus on factual, evidence based, technical content for standards that are made within broader policy environments.

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

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

Answer:

At this stage, ISDI favours that current provision 9.6 in the Codex standard for follow-up formula remains.

To ensure that these products are not marketed as breastmilk substitutes, appropriate Codex guidelines on labelling of these products should be defined such as:

- Recommended age of introduction
- No image of an infant younger than 6 months

Important message on the label that state clearly and legibly that breastfeeding is best up to two years and beyond and that this product is not a breastmilk substitute.

ISDI notes there are significant difference between the compositional criteria proposed for follow-up formula for young children compared to follow-up formula for older infants as well as their role in the diet.