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**

To: Jenny.Reid@mpi.govt.nz; Alice.STENGEL@dgccrf.finances.gouv.fr; codexbpom@gmail.com

Please provide your responses to the first consultation paper in the response form below. Note, to fill in a check box please right click on the box and select “Properties”, under the “Default Action” sub-heading, select “Checked”.

Name of Member Country/Organisation: **­­­­­­­­­­­­­­­­­­­­­­­­­­­­­ INTERNATIONAL DAIRY FEDERATION**

**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** g/100 kcalg/100 kJ | **Minimum**[1.8] or [1.65][0.43] or [0.39] | **Maximum**[3.5] or [3.0] or [2.5][0.84] or [0.72] or [0.60] | **GUL**-- |
| **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:IDF refers to its previous position submitted 37th CCNFSDU, that consideration of the safe minimum content of protein needs to ensure that the product achieves the required indispensable amino acid profile and with adequate “bioavailability”- ie protein quality |
| **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:** As outlined in 37th session of CCNFSDU, IDF continues to support a maximum protein level of 3.5 g/100 kcal and reiterates its previously submitted comments justifying this approach. IDF 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:** Global Codex Standards must cover a broad range of nutritional requirements, where protein intakes (both quantity and quality) vary by setting, and under and over nutrition may co-exist. Protein levels in a Std should enable sufficient protein intake of older infants living in both developed and developing countries. **Scientific substantiation*:***Scientific evidence is core in establishing the revised Codex Standard for Follow-Up Formula for older infants. Establishing the upper protein level for follow up formula for older infants requires assessment of the totality of scientific evidence regarding safety and suitability of the maximum proposed protein level. Neither EFSA (2014) nor WHO/FAO (2007) established an upper safe limit for protein for older infants, as there was insufficient evidence to guide this. The maximum proposed protein limit of 3.5 g protein/100 kcal is safe and suitable for consumption by older infants, has a long history of apparent safe use and has been globally marketed since the origin of the Codex Standard for Follow-up Formula (Codex STAN 156-1987). We further note that:• 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 the above 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.• We Note the results of a recent systematic review of protein levels of formula for infants in Europe (Patro Golab et al, 2016) that found limited evidence in support of the proposed relationship between protein intakes in infancy and later risk of childhood obesity, and concluded that evidence was insufficient for assessing the effects of reducing the protein concentration in infant formulas on long-term outcomes. The one randomized controlled trial that supports the early protein hypothesis (Koletzko et al. 2009) tested a Follow-Up Formula for older infants at a higher protein level (4.4g/100kcal) than is being proposed at 3.5g/100kcal.• Considerations should be given to the diversity of protein intakes across the globe in establishing the maximum protein level, which should enable to both protein intake of older infants living in developed and developing countries. 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 the majority of developed countries meet protein requirements, noting that average intakes do not reflect population intake distribution data (Gibney 2004) and therefore are not suitable to identify those with intakes below recommended levels. More limited data is available from developing countries. Surveys in Philippines, Vietnam, Malaysia, Indonesia indicate average intakes of older infants meet protein requirements, however a significant proportion still did not meet local NRVs (noting comparison to WHO protein safe levels was not published) as summarized in Table 1. This data indicates there is continued benefit and a need for products to remain on the market with a protein density of 3.5g/100kcal. Adequate protein quality is particularly important for children consuming complementary diets that contain little animal protein or when quality of other protein sources may be limited. As acknowledged by WHO (2005), populations with predominantly plant based diets would benefit from higher intakes of high quality protein, reflected in the recommendation for higher milk consumption. It is therefore important a **global** FuF Std continues to encompass a range of products and cater for global nutrition needs.* International trade related aspects:

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.The maximum proposed protein limit of 3.5 g protein/100 kcal is safe and suitable and also supports continuity of trust and international trade of follow-up formula for older infants compliant with the current and revised standards..*References*Butte NF, Fox MK, Briefel RR, *et al.* (2010) Nutrient intakes of US infants, toddlers, and preschoolers meet or exceed dietary reference intakes. *Journal of the American Dietetic Association*, 110:S27-S37. de Boer EJ, Hulshof KFAM, ter Doest D (2006) *Voedselconsumptie van jonge peuters [Food consumption of young children]*. TNO rapport V6269, 37 pp.DGE (Deutsche Gesellschaft für Ernährung) (2008), *Ernährungsbericht 2008 [Nutrition Report 2008]*. Deutsche Gesellschaft für Ernährung, Bonn, Germany, 442 pp. EFSA (2013) Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. *EFSA Journal*, 11(10):3408.FNRI, Department of Science and Technology. 2008 National Nutrition Survey. Food Consumption Survey Component. Individual Food and Nutrient Intakes. <http://fnri.dost.gov.ph/images/sources/food_consumption_individual.pdf>Fantino M, Gourmet E (2008) Apports nutritionnels en France en 2005 chez les enfants non allaités âgés de moins de 36 mois [Nutrient intakes in France in 2005 by non-breast fed children of less than 36 months]. *Archives de Pédiatrie*, 15:446–455. Gibney MJ, Margetts BM, Kearney JM, Arab L (2004) Public Health Nutrition. The Nutrition Society Textbook Series. Blackwell Publishing, OxfordHarvey P, Rambelosen Z, Dary O. The 2008 Uganda food consumption survey. Determining the dietary patterns of Ugandan women and children. Washington, DC: Academy for Educational Development; 2010. <https://www.spring-nutrition.org/sites/default/files/a2z_materials/508-uganda_food_consumption_survey_final_08152011.pdf>Hilbig A (2005) Längerfristige Trends bei der Ernährung von Säuglingen und Kleinkindern der DONALD Studie im Zeitraum 1989 – 1999 [Long-term trends in the nutrition of infants and young children of the DONALD study from 1989-1999]. Inaugural dissertation at the Justus-Liebig-Universtität Gießen. 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.1Institute of Medicine, Food and Nutrition Board (2002) Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, DC: National Academies Press.Koletzko B, von Kries R, Closa R *et al*. (2009) Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial. *Am J Clin Nutr* **89**:1836-1845Lagström H, Jokinen E, Seppanen R, *et al.* (1997) Nutrient intakes by young children in a prospective randomized trial of a low-saturated fat, low-cholesterol diet. The STRIP Baby Project. Special Turku Coronary Risk Factor Intervention Project for Babies. *Archives of Pediatrics and Adolescent Medicine*, 151:181-188. Lennox A, Sommerville J, Ong K, *et al.* (2013*)* Diet and nutrition survey of infants and young children, 2011. A survey carried out on behalf of the Department of Health and Food Standards Agency. http://webarchive.nationalarchives.gov.uk/20130402145952/http://transparency.dh.gov.uk/2013/03/13/dnsiyc Marriott LD, Robinson SM, Poole J, *et al.* (2008) What do babies eat? Evaluation of a food frequency questionnaire to assess the diets of infants aged 6 months. *Public Health Nutrition*, 11:751-756. Noble S, Emmett P (2001) Food and nutrient intake in a cohort of 8-month-old infants in the south-west of England in 1993. *European Journal of Clinical Nutrition*, 55:698-707. *Nguyen BKL, Thi HL, Do VAN et al. Double burden of undernutrition and overnutrition in Vietnam in 2011: results of the SEANUTS study in 0.5-11 year old children. Br J Nutr 2013;110:S45-56.* WHO/FAO/UNU (2007) Protein and amino acid requirements in human nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation. WHO Technical Report Series, No 935, Geneva. |
| **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.It is noted that since the publication of Codex STAN 72-1981 and its Annex I, new publications have described the amino acid profile in human milk including recent systematic reviews (Zhang 2013, Lönnerdal 2016). However the amino acid levels are considered sufficiently close to earlier references that a full review is not considered justified at this time.Annex I of Codex STAN 72-1981 describes the levels of essential and semi-essential amino acids expressed per g of nitrogen from each study and derives from this the per g of protein and per 100kcal expressions for a minimum protein of 1.8g/100kcal. IDF suggests a similar approach for follow-on formula but applying the minimum set for Follow-up formula for older infants.The FAO has acknowledged the importance of using human milk as the scoring pattern for protein quality in infants for a number of years (FAO/WHO, 1991), and consider the growth and metabolic state of a breast fed infant as the normative standard for this age. They also acknowledged that the digestibility and bioavailability of amino acids are important factors as not all dietary proteins are digested and utilized to the same extent (FAO/WHO, 1991). In 2013 an FAO Expert Consultation on dietary protein quality was held. The expert consultation provides an update and improvements to the Protein Digestibility Corrected Amino Acid Score (PDCAAS) method for measuring dietary protein quality, referred to as Digestible Indispensable Amino Acid Score (DIAAS). The key findings of the report are that dietary amino acids should be treated as individual nutrients, and that for regulatory purposes two amino acid scoring patterns are recommended: birth to six months; and 6-36 months, and that if protein quality of FUF needs to be assessed then the most up-to-date method should be used. The DIAAS methodology maintains that the breast milk pattern is still the desired target, however, it provides understanding of whether the protein provides available amino acids to meet the requirements of 0-6 and 6-12month infants. The FAO Expert Working Group’s report (2014) recommended the adoption of the DIAAS method by Codex, however also recognised that there is further work to be completed to ensure a supporting framework to enable full implementation of the DIAAS method. Global coordinating efforts to advance method validation and build a large database to enable wide use and application of DIAAS are currently underway.We consider implementation of DIAAS as a protein scoring system, with suitable age related targets as recommended by the FAO, will provide additional clarity to the formulation of Follow-Up Formula for 6-12months, and ensure that proteins used in formula will deliver a suitable level of available amino acids to the infant. ReferencesLönnerdal Bo, Erdmann Peter, Thakkar Sagar K., Sauser Julien, Destaillats Frédéric (2016). Longitudinal evolution of true protein, amino acids, and bioactive proteins in breast milk: a developmental perspective. Journal of Nutritional Biochemistry doi: 10.1016/j.jnutbio.2016.06.001. Zhang Z, Adelman AS, Rai D, Boettcher J, Lőnnerdal B (2013). Amino acid profiles in term and preterm human milk through lactation: a systematic review. Nutrients. 2013 Nov 26; 5(12):4800-21.FAO. (2013). Dietary protein quality evaluation in human nutrition. Report of an FAO Expert. FAO FOOD AND NUTRITION PAPER 92.(accessed on 18.06.2015; http://www.fao.org/ag/humannutrition/35978-02317b979a686a57aa4593304ffc17f06.pdf) FAO. (2014). Research approaches and methods for evaluating the protein quality of human foods. Report of a FAO Expert Working Group 2 – 5 March 2014 Bangalore, India. (accessed on 18.06.2015; http://www.fao.org/3/a-i4325e.pdf) FAO/WHO (1991). Protein Quality Evaluation: Report of Joint FAO/WHO Expert Consultation, Rome |
| Footnote 6The 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. |
| 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.* |
| Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required forany 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.* |
| **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  |
|  |

**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** mg/100 kcalmg/100 kJ | **Minimum**41 | **Maximum**-- | **GUL**276.5 |
|  |
| *Please comment on this proposal and provide your justification*: |

**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 C15)****Unit** mg/100 kcalmg/100 kJ | **Minimum**[10] [4][2.5] [0.96] | **Maximum**-- | **GUL**7016)1716) |
| **15)** expressed as ascorbic acid16) 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 kJTaking a precautionary approach and aligned with the Codex Infant Formula Standard | ☐ EFSA  4 mg/100 kcal 0.96 kJ/100 kcalBased on vitamin C requirement levels established by EFSA, taking into account that complementary foods are consumed from six months.  |
| *Please provide your preferred response*: |

**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** mg/100 kcalmg/100 kJ | **Minimum**0.50.12 | **Maximum**-- | **GUL**1.50.36 |
| 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*:  |

|  |
| --- |
| **Docosahexaenoic acid (DHA)** |
| Please provide scientific justificationto support your preferred value in square brackets: |
| **Docosahexaenoic acid21)****Unit** % fatty acids | **Minimum**[-] or [0.3] | **Maximum**- | **GUL**0.5 |
| **21)** If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, **[a minimum of [x% fatty acids] should be added** arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs. |
| If added, minimum level  |
| ☐ No minimum level specified | ☐ 0.3% fatty acids | ☐ Other please specify:  |
| *Please provide scientific justification for your response*: |
| If you indicated that a minimum DHA content was warranted if added, please specify whether this requirement should be placed footnote 21 or in the table. |
|  |

**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** |
| 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*: |

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

**Proposed approach**

|  |
| --- |
| **Mandatory (core) composition** |
| Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is :* Evidence to support nutritional issues for young children of global concern;
* Contribution to the overall nutritional quality/integrity of the product;
* The contribution of key nutrients from cows milk for equivalence; and
* The strength of committee support for including in the core composition.
 |
| *Answer:*Yes – IDF supports the approach taken for defining mandatory composition of Young Child Formula (YCF).IDF supports an approach that allows for nutritional equivalence of milk composition thereby recognizing the numerous WHO dietary guidelines on the importance of milk in the diet and milk as an important ingredient in such products for this age category. Regarding mandatory maximum nutrient limits, IDF considers these should only be introduced for nutrients that are of concern/ have upper safe levels established and that are added in levels not reflective of cow’s milk (e.g. refined carbohydrates/free sugars, industrial TFA), and that may not be adequately controlled for by the energy range. In defining nutrient composition, due consideration must also be given to how this may be achieved from an ingredients formulation perspective.IDF refers to the overarching principles guiding the development of the overall compositional profile for the 12-36 month age group, including increased flexibility and less prescription.  |
| 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:* |
| **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:* |
| **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:* |
| **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:* |
| **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:* |
| **QUESTION:**Do you support deletion of the third bullet point for follow-up formula for young children?  |
| **Answer:***Please provide justification for your answer:* |

**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:*Review of recommended macronutrient percentage contribution to overall energy (% of energy) may be used to help inform macronutrient ranges within the Standard, however these ranges should not be looked at in isolation, and cow’s milk composition must also be considered.AMDR/DRI/ Macronutrient distribution ranges guide **total** dietary daily intake of nutrients and are not intended for development of foods that are not a sole source of nutrition/ meal replacement. While one way to develop macronutrient minimums may be to refer to minimum levels of these ranges, **it is not appropriate to base nutrient limits in a complementary food product (i.e. YCF) solely on these ranges.** Different foods provide different proportions of macronutrients, therefore contributing to the total macronutrient intake in unique ways. **When setting macronutrient ranges for a product that typically replaces/ substitutes cow’s milk in the diet, it is important to consider the macronutrient range in cow’s milk when defining appropriate macronutrient minimum and maximum levels for this standard, including the ingredient combinations necessary to achieve the desired macronutrient profile.** IDF notes that milk forms an important basis of such products. Milk is recognized as an important part of a healthy diet for young children with >40 countries recommending its consumption (FAO, 2013). WHO specifically recommends in feeding guidelines for the non-breast-fed child age 6-24 months “*If adequate amounts of other animal-source foods are consumed regularly, the amount of milk needed is ~200-400 mL/d; otherwise, the amount of milk needed is ~300-500 mL/d*”, acknowledging the important role that milk plays in growing children’s diets (WHO 2005). As such, consideration of milk macronutrient %/density, and energy density, form an important basis to help guide development of the Std. IDF is supportive of macronutrient ranges/ density/ % that allows for that in milk (e.g. energy & fat), noting that whole milk is recommended as an important source of fat for children up to two years of age, and for those who wish reduced fat milk may be consumed from 12 months of age (while skimmed milk should not be given in the first 2 years of life) (WHO 2005).Whole milk macronutrient levels are typically 22%E protein, 48%E fat, and 30%E carbohydrate (lactose) (FAO, 2013, \* converted using average milk energy density of 62kcal/100g). Reduced fat milk (1.5%) macronutrient levels are around 30%E protein, 27%E fat and 42%E carbohydrate (lactose)\*.**Table 1**. IDF suggested macronutrient ranges for 12-36month YCF, with with comparison to the equivalent g/100kcal amount, and reduced fat and whole cow’s milk levels.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|   | **IDF Suggested (Range %E)** | **IDF Suggested****(g/****100 kcal)** | Whole Milkg/100kcal\* | Reduced-fat Milk (1.5%)g/100 kcal\* | **Justification** |
|  Energy |  45-70kcal/100mL |   | 62kcal/100mL | 46kcal/100mL | An energy range of 45-70kcal/100mL is supported on the basis of minimum level equivalent to reduced fat milk & upper level comparable to the upper range of whole cow’s milk. This delivers approx. 15-22% energy to the total diet if an average consumption of 300mL/ day is calculated. |
| Protein | X-22% | X-5.5g | 5.5g | 7.6g | **Minimum:** Must ensure adequate protein is delivered from the product.**Maximum**: Not required or otherwise:GUL 5.5g/100kcal: This enables products formulated predominately based on cow’s milk to be included in scope. Whole milk has a protein density of ~5.5g/100kcal which equals around 21-22%E, with reduced fat milk having higher levels as summarised by eWG. |
| Fat | >32% | >3.5g | 5.3g | 3.0g(eWG average level in reduced-fat milk (1.5-2% fat = 3.5g/ 100kcal) | **Minimum**:Similar to the energy approach, whereby minimum energy was defined a levels comparable to reduced fat milk, minimum fat may be defined by the fat density of reduced fat milk –outlined by eWG approx. 3.5g/100kcal (avg) **Maximum**: Not required or otherwise 54%E (equals 6g/100kcal – same as the current IF Std).We note younger children are advised to consume full fat milk products because of their higher energy & essential fatty acid requirements, although reduced fat milk may be consumed from 12 months (however, semi skimmed milk should not be given for the first 2 years of life) (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.Increased fat levels also support reduced addition of added CHO (including refined CHO and sugars) ingredients in the product. The upper range of 6g/100kcal is greater than the EU total diet RI 35-40% for young children, however this product is not a meal replacement, and not every food must align to total diet intake distribution; furthermore, other foods provide little or no fat. |
| CHO | tbc |  | **7.6g** | **10.4g** | **Minimum:** Not necessary. IDF recommend >50% of the CHO in the product is from lactose**Maximum:** Total CHO should be restricted to limit refined CHO/ added sugars. This cap will be dependent on minimum protein levels once defined, & while a low fat level is defined, CHO cap may be based on a higher fat level in order not to fill with added CHO ingredients. |

\*FAO 2013; \*\*NZ Food Composition Tables 11th edition 2014ReferencesFAO (2013) Milk and dairy products in human nutrition. Food and Agriculture Organization of the United Nations, Rome.WHO (2005) Guiding principles for feeding non-breastfeed children 6-24 months of age. World Health Organization, Geneva.\*(based on energy density of 46kcal/100g; source: New Zealand Food Composition Tables 11th edition) |

**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** kcal/100 mlkJ/100 ml | **Minimum**[60] [45][250] [188] | **Maximum**[70][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 88 kJ/100 ml  |
| *Please provide justification for your answer*IDF supports the range for the energy density of follow-up formula for young children accommodating the energy content of whole cow’s milk, which WHO recommends as an important source of fat in the first 2 years of life of non-breastfed children (WHO, 2005). As the Standard covers an age range up to 36 months the appropriate range of energy density needs to be considered for all age >24months. Therefore IDF supports a minimum energy level of 45kcal/100mL and a maximum of 70kcal/100mL which encompasses the energy range of reduced fat milk (1.5% fat) and whole milk.ReferenceWHO (2005) Guiding principles for feeding non-breastfeed children 6-24 months of age. World Health Organization, Geneva. |
| 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:*IDF 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. IDF considers the maximum defined in the revised draft 6-12month section of the Follow-Up Formula Standard of 70kcal/100mL to be appropriate, noting that this encompasses the energy density of whole cow’s milk. |

**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**Minimum*IDF considers it is critical that adequate minimum protein levels are set. Protein is essential for growth & development, and milk is an important source of high quality protein in young children’s diets. As the product may replace milk in the diet, the substitution of milk with a product without adequate protein levels could negatively impact the ability to meet RDIs for protein, and may therefore impact growth & development. A protein minimum also defines a minimum milk content of the product and thus avoids excess addition of refined carbohydrate ingredients. We also continue to plead that safe minimum content of protein needs to ensure that the product achieves the required indispensable amino acid profile and with adequate “bioavailability”- ie protein quality. Maximum: **Upper Limit – 5.5g/100kcal or N.S.**IDF does not consider it necessary to establish a maximum protein level, noting there is no UL for this nutrient; however, if an upper limit is to be established IDF supports 5.5g/100kcal, reflecting levels found in whole milk. IDF notes that Codex Standards are for global use, where both over- and under-nutrition are an issue across countries. Studies have indicated FuF 12-36mo products **are used as a substitute for cow’s milk (Alexy & Kersting, 2003)**; protein ranges need to therefore cater to a diverse consumer base **and continue to incorporate protein levels reflective of cow’s milk (~5.5g/100kcal)**. IDF therefore supports a broad range of protein levels that continue to encompass the protein density of cow’s milk at **~**5.5g/100kcal and therefore allow products predominately based on milk to still be included within the Standard i.e. a GUL of 5.5g/100kcal.Milk as the basis/ an important ingredient in such productsDietary guidelines globally recommend milk consumption, including in young children, and milk levels have been used to guide both fat minimum and energy ranges in the YCF Standard. It is important the Standard continues to enable formulation of products made predominantly from milk, with little addition of added refined carbohydrate.The World Health Organisation acknowledges the importance of cow’s milk in growing children, and whole milk is recommended by the WHO guidelines for non-breast fed children from 6-24 months as a valuable source of protein (along with other essential nutrients; WHO 2005). The importance of milk for growing children is also reflected in numerous national guidelines (FAO > 23 countries). The protein content of whole cow’s milk ranges between **3.2 to 3.6g/100 ml** (FAO 2013, Ref), 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). According to the WHO, reduced-fat milk may be introduced from age 12 months (however skimmed milk should not be given in the first two years of life) (WHO 2005). Reduced fat milk has a higher protein density of around 7.6g/100kcal. (based on an energy density of 46kcal/100mL and a protein content of 3.5g/100mL; New Zealand Food Composition Tables 11th edition 2014). The current Codex Standard for follow-up formula has a maximum protein limit of 5.5g/100kcal which continues to enable a formulation produced predominately from milk with limited carbohydrate addition. Protein (in)adequacy in young childrenData from developing countries is limited, with nationally representative protein intake distribution data unavailable from the majority. Despite *average* protein intakes being above RDAs in India, Indonesia and China, 21%, 32-52%, 6-10% of young children surveyed had intakes below WHO minimum safe levels, the Indonesia RDA or China EAR protein requirements, respectively as summarized in Table 1 below (NIN ICMR 2012, Sandjaja 2013, Babarich, 2006). In the Philippinnes (FNRI, 2008), average intakes for 6month to 5year olds were 26.1g, while only 48% met the local EAR (calculated as being 80% of the RENI). In Bangladesh not even average intakes were meeting minimum requirements (Yakes et al. 2011), suggesting that a large proportion of children have intakes below safe levels, which is concerning. In light of the high prevalence of underweight and stunting in a number of regions (WHO 2014), and the well documented negative health consequences of inadequate protein intakes on immunity, brain function, and growth & development (IOM, 2001), a number of children will continue to benefit from products with a higher proportion of energy from protein, in particular high quality protein. It is therefore **critical a global FuF Std for young children continues to encompass a range of products, including those with protein levels reflective of whole cow’s milk ~5.5g/100kcal.**Protein Intakes and proposed link with obesity, insufficient evidence to establish a maximum/ infer that milk protein levels should be avoidedIt is noted that there has been considerable discussion regarding protein intakes in infancy and risk of obesity. However, current evidence is too limited to support a proposed link between protein intake in infancy and risk of obesity, and **does not justify any reduction in the existing maximum protein levels of 12-36month young child formula in the context of a global standard.*** A recent systematic review (Patro-Golab et al 2016) included 12 RCTs and found that only one Randomised Controlled Trial (RCT) supported the early protein hypothesis (Koletzko et al. 2009), and that overall evidence was insufficient for assessing the effects of reducing the protein concentration in infant formulas on long-term outcomes. (Of note, while in the study by Koletzko et al. those consuming formula with higher protein content up to 12 months had higher BMI at age 6 years compared to those consuming the lower-protein formulas, there was no significant difference in BMI between the higher protein group and the breastfed children after adjustment for the various confounding factors.)
* Another RCT has since been published that does not support the early protein hypothesis as it found no effect on growth hormones that have been suggested to mediate a proposed effect of protein on risk of obesity. While lower protein was associated with less growth (weight, length, head circumference), there was no difference in fat mass or fat-free mass between lower and higher protein formula groups (noting that lower protein formula fed infants had significantly higher fat mass than breastfed children, while the higher protein group was not significantly different from the breastfed group) (Putet et al. 2016)
* While some (but not all) observational studies support a link between protein intakes in early life (12+months) and risk of overweight/obesity in children, these often do not adequately adjust for key confounders and no cause-effect relationship can be drawn from observational studies (Öhlund et al. 2010; Günther et al. 2007; Scaglioni et al. 2000). A recent, large observational study found no significant difference in mean BMI, weight or height up to 36 and 60 months when comparing the higher to the lowest quintile of protein intake at 21 months of age. Although linear-mixed effect modelling suggested an association between protein intake and BMI, the overall effect size was small and likely not clinically significant (Pimpin et al. 2016). While another recently published observational study found a significant association between total protein intake at 1 year and BMI and fat mass index (FMI) at 6 years, the effect size was small (10g more protein per day resulted in 0.06 higher FMI score, which equals 84g more fat mass from age 1-5 years) and was no longer significant for BMI when baseline BMI was adjusted for. Further analysis showed that association was only present in children who had catch-up growth ($\~$20%), but not in the majority of children who did not have catch-up growth ($\~$80%), suggesting that there is no association between protein and BMI or FMI in the majority of children who have normal growth early in life (Voortman et al. 2016).

Furthermore, the proposed link between protein intake in infancy and increased risk of overweight and obesity is in contrast to evidence in childhood on the link between increased dairy consumption (noting Follow Up Formula for 12-36 months is a product based on milk) and reduced risk of overweight and obesity. * A systematic review and meta-analysis of prospective cohort studies by Lu et al (2016) found that children who had high dairy intakes (a significant source of protein in children’s diet) had a 38% lower risk of childhood overweight/obesity compared to children with low dairy intakes. Of note, three of the four prospective cohort studies included in this meta-analysis were in children that were 2-2.5 years old at baseline, i.e. the findings are relevant for our target age group. Dairy protein, alongside calcium, has been suggested as a dairy component that may partly explain this inverse association of dairy and reduced risk of overweight/obesity. **These findings are in line with evidence of a beneficial effect of dairy with its inherent protein density on body weight (in particular body fat mass) in adults (**Abargouei et al. 2012; Chen et al. 2012; Booth et al. 2015; Rautiainen et al. 2016)**.**

Quality ParametersFormula for 12-36months has been shown to be used in the diet as a substitute for cow’s milk consumption (Alexy & Kersting, 2003). Cow’s milk protein is high quality due to its proportion of indispensable amino acids and high digestibility – therefore quality parameters should seek to ensure nutritional equivalence to the protein in cow’s milk using the most recently recognized protein scoring system DIAAS once appropriate framework in place. This is particularly important for those complementary diets that contain little animal protein or when quality of other protein sources may be limited. As acknowledged by WHO (2005), populations with predominantly plant based diets would benefit from higher intakes of high quality protein, reflected in the recommendation for higher milk consumption. CODEX standards are global and so have to address global nutrition issues. Reference:Abargouei AS, Janghorbani M, Salehi-Marzijarani M, Esmaillzadeh A. (2012) Effect of dairy consumption on weight and body composition in adults: a systematic review and metaanalysis of randomized controlled clinical trials. Int J Obes (Lond) 2012; Jan 17 (Epub ahead of print; DOI: 10.1038/ijo.2011.269).ANSES French Agency for Food, Environmental & Occupational Health – Table Ciqual. Accessed xxAlexy U, Kersting M. Time trends in consumption of dairy foods in German children and adolescents. Eur J Clin Nutr 2003; 57:1331-1337Barbarich BN, Willows ND, Wang L, Clandinin MT: Polyunsaturated fatty acids and anthropometric indices of children in rural China. Eur J Clin Nutr 2006; 60: 1100–1107Booth AO, Huggins CE, Wattanapenpaiboon N, Nowson CA (2015) Effect of increasing dietary calcium through supplements and dairy food on body weight and body composition: a meta-analysis of randomised controlled trials. Brit J Nutr 114:1013-1025. Chen M, Pan A, Malik VS, Hu FB. (2012) Effects of dairy intake on body weight and fat: a meta-analysis of randomized controlled trials. Am J Clin Nutr 2012. doi: o 10.3945/ajcn.112.037119.EFSA, Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013; 11(10):3408.FAO (2013) Milk and dairy products in human nutrition. Food and Agriculture Organization of the United Nations, Rome.FNRI, Department of Science and Technology. 2008 National Nutrition Survey. Food Consumption Survey Component. Individual Food and Nutrient Intakes. <http://fnri.dost.gov.ph/images/sources/food_consumption_individual.pdf>Food and Nutrition Research Institute (2012) Philippine Nutrition Facts and Figures 2011. Department of Science and Technology, Taguig City.Günther ALB, Buyken AE & Kroke A (2007) Protein intake during the period of complementary feeding and early childhood and the association with body mass index and percentage of body fat at 7 y of age. Am J Clin Nutr 85:1626-1633.Institute of Medicine (2001) Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. The National Academies Press, Washington DCLu L, Xun P, Wan Y et al. (2016) Long-term association between dairy consumption and risk of childhood obesity: a systematic review and meta-analysis of prospective cohort studies. Eur J Clin Nutr doi:10.1038/ejcn.2015.226Öhlund I, Hernell O, Hörnell A et al. (2010) BMI at 4 years of age is associated with previous and current protein intake and with paternal BMI. Eur J Clin Nutr 64:138-145.Putet G, Labaune JM, Mace K et al. (2016) Effect of dietary plasma insulin-like growth factor-1, growth, and body composition in healthy term infants: a randomised, double-blind, controlled trial (Early Protein and Obesity in Childhood (EPOCH) study). Brit J Nutr 115(2):271-84. Patro-Golab B, Zalewski BM, Kouwenhoven SMP et al. (2016) Protein concentration in milk formula, growth, and later risk of obesity: a systematic review. J Nutr doi:10.3945/jn.115.223651.Pimpin L, Jebb S, Johnson L *et al.* (2016) Dietary protein intake is associated with body mass index and weight up to 5 y of age in a prospective cohort of twins. *Am J Clin Nutr*, doi:10.3945/ajcn.115.118612. Rautiainen S, Wang L, Lee IM et al. (2016) Dairy consumption in association with weight change and risk of becoming overweight or obese in middle-aged and older women: a prospective cohort study. Am J Clin Nutr doi: 10.3925/ajcn.115.118406.Sandjaja, Budiman B, HarahapH, Ernawati F, Soekatri M, Widodo Y, (2013): Food consumption and nutritional and biochemical status of 0.5–12-year-old Indonesian children: the SEANUTS study. Br J Nutr; 110(suppl 3):S11–S20.Scaglioni S, Agostini C, De Notaris R et al. (2000) Early macronutrient intake and overweight at five years of age. Int J Obes 24:777-781.Voortman T, Braun KVE, Kiefte-de Jong JC et al. (2016) Protein intake in early childhood and body composition at the age of 6 years: The Generation R Study. Int J Obes 40:1018-1025. Wang X, Hojer B, Guo S et al. (2009) Stunting and ‘overweight’ in the WHO Child Growth Standards – malnutrition among children in a poor area of China. Public Health Nutrition 12(11):1991-1998.WHO (2005) Guiding principles for feeding non-breastfeed children 6-24 months of age. World Health Organization, Geneva.WHO (2009) Protein and amino acid requirements in human nutrition. WHO Technical Report Series No 935. Geneva, Switzerland.WHO (2014) WHA Global Nutrition Targets 2025: Stunting Policy Brief. Available online: <http://www.who.int/nutrition/topics/globaltargets_stunting_policybrief.pdf> (accessed 15 February 2016)WHO Report of a Joint FAO/WHO Expert Consultation. Diet, Nutrition and prevention of chronic disease. WHO Technical Report Series 916Yakes EA, Arsenault JE, Islam MM, Ahmed T, German JB, Drake C, et al: Dietary intake of polyunsaturated fatty acids among breastfeeding and non-breast-feeding 24- to 48-month-old children in Bangladesh. J Pediatr Gastroenterol Nutr 2011; 52: 351–359. |
| 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*IDF believes consideration must be given to protein quality and methods to assess protein quality.IDF consider DIAAS is the most accurate method for assessing protein quality, and should incorporate the most relevant amino acid reference pattern for young children. Breast milk amino acid profile is not the most relevant reference pattern for this product.  |

**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*IDF notes younger children are recommended to consume whole milk, however from age 2 years may also be offered reduced fat milk options. Thus it is appropriate that the minimum fat levels in YCF should not be lower than reduced fat milk in order to cover the broad age range.Therefore minimum fat levels may be guided by reduced fat milk (1.5% fat). This will enable formulations targeting the lower level of the energy range to be produced and is consistent with the lower energy range of 45kcal/100mL.  |
| 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 specifyNot Specified |
| *Please provide justification for your answer*In line with the principles of increased flexibility, IDF does not consider a fat maximum to be necessary. This is self-limiting in order to formulate to the energy range. However, if a max is to be specified 6g/100kcal is supported on the basis of a) upper levels of whole milk, and b) level in current FuF Std.IDF notes the maximum fat level of 6g/100kcal is greater than the EU total diet RI 35-40% for young children and results in 55% of energy in the product from fat; however, this product is not a meal replacement, and not every food must align to total diet intake distribution. Furthermore, other foods may provide reduced fat. |

**Lipids**

|  |
| --- |
| **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.*IDF refers to key principles outlined in earlier sections.IDF would like to highlight that milk fat contains approximately 400 different fatty acids, which makes it the most complex of all natural fats (FAO, 2013). All of these fatty acids play an intricate role in the physiologic effects of milk. Therefore the fatty acid profile of Follow-up Formula should be closely aligned with the fatty acid profile of cow’s milk. **Linoleic Acid**IDF considers there is insufficient justification to mandate minimum LA levels, and that this would not be in line with the key overarching principles defined by the eWG.* There is insufficient evidence to suggest intakes of LA are globally limited in a young child’s diet. Food supply data does not indicate this is insufficient (Michaelsen, 2011). EFSA concluded intakes and status of LA were of no concern for European infants and young children (EFSA 2013).
* YCF products either made predominately from milk (with added key mandatory nutrients of global concern) or with milk and added vegetable oils, will naturally contain LA. Mandating LA at levels higher than minimum levels in cow’s milk will not allow products predominately based on milk to be included in scope.
* If the decision is made to mandate this nutrient, IDF suggests this level is not greater than that in the current FuF Std of 300mg/100kcal.

**Alpha-Linolenic Acid**IDF is of the view that minimum ALA minimum levels are not necessary to be defined in the YCF Standard, and notes that levels of ALA will naturally be present in YCF from the milkfat..* IDF notes there is limited evidence regarding global intakes of ALA specifically in young children, and thus considers this nutrient does not fulfill sufficient criteria to include in the mandatory compositional profile for the YCF Standard.
* EFSA (2013) outlined intake data of fatty acids was scarce in the EU, and of the data available, that dietary intakes of omega 3’s ALA and DHA in young children were low relative to the Adequate Intake; however, that in the absence of a clear relationship between intakes or biomarkers of n-3 PUFA status and clinical outcomes, the risk of inadequate intakes of ALA and DHA in infants and young children living in Europe cannot be quantified. The Panel identified YCF or fortified cow’s milk as some of the means to increase intake of these nutrients (along with inadequate intakes of iron, vitamin D and iodine)*.*
* If minimum ALA levels are to be defined, these could incorporate minimum levels in milkfat in order to support products predominately based on milk that meet other mandatory compositional parameters within the Standard.
* If higher levels are to be mandated, minimum levels could be defined based on minimum FAO requirements i.e. 0.4% of total energy from ALA, which could be applied to the whole product (although we note that applying recommended macronutrient ranges (i.e. AMDR, RDI) to single foods is generally not appropriate, but in absence of other RDIs may be one way for establishing minimum nutrient levels). This approach equals ~~to~~ 44mg/100kcal (i.e. 0.4% of 100kcal = 100\*0.004/9).

**Ratio**IDF is of the opinion it is not necessary to mandate an LA:ALA ratio for YCF.* YCF is consumed as part of a mixed diet, LA and ALA will be introduced from milkfat and/or vegetable sources of fat in the product, along with a variety of other foods in the diet that deliver these nutrients.
* There is insufficient evidence in young children to define an optimal LA: ALA ratio in a YCF product. Furthermore, as outlined by FAO (Ref ) “*Based on both the scientific evidence and conceptual limitations, there is no compelling scientific rationale for the recommendation of a specific ratio of n-6 to n-3 fatty acids or LA to ALA, especially if intakes of n-6 and n-3 fats lie within the recommendations established in this report*”

**Phospholipids**IDF does not consider it necessary to establish levels for phospholipids in the YCF Standard. IDF notes that phospholipids occur naturally in the cow’s milk and lecithin base ingredients of YCF. Toddlers will eat a variety of foods that contain PL. There is no strong scientific justification to set an upper phospholipid level. This nutrient does not have an USL, there is no evidence of adverse effects of PLs in young children, and an absence of market failure of the current FuF Standard which does not set an upper limit.**Maximum TFA content**As outlined below, IDF does not support introduction of a TFA limit; however, does support restriction of industrial TFA addition to YCF through prohibition of addition of hydrogenated vegetable oils.ReferenceFAO (2013) Milk and Dairy Products in human nutrition. (<http://www.fao.org/docrep/018/i3396e/i3396e.pdf>, accessed on 7 July 2016) EFSA (2013). EFSA Panel on Dietetic Products, Nutrition and Allergies. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal;11(10):3408 |
| 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 justification for your answer.  | ☒ No |
| 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. | ☒ No |
| 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.***TFA** IDF notes that the focus for public health bodies is on reducing **industrial** TFA intake but not ruminant TFA intake. To this end, IDF is supportive of retaining text within the FuF Std that restricts the addition of **hydrogenated vegetable oils**, as these are the only sources of industrial trans fats in formula. If this clause is retained, IDF does not consider it necessary to mandate a % TFA of total fat.The detrimental effects of industrial TFA on heart health are well accepted:* A 2009 WHO Scientific update on TFA concluded that:

‘*The current growing body of evidence from controlled trials and observational studies indicates that TFA consumption from* ***partially hydrogenated oils*** *adversely affects multiple cardiovascular risk factors and contributes significantly to increased risk of CHD events.* *TFA produced by* ***partial hydrogenation*** *of fats and oils should be considered industrial food additives having no demonstrable health benefits and clear risks to human health.’ (Uauy, 2009)* * The 2010 FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition contains similar conclusions on industrial TFA:

‘*There is convincing evidence that TFA from commercial* ***partially hydrogenated vegetable oils*** *(PHVO) increase CHD risk factors and CHD events – more so than had been thought in the past.**There is also probable evidence of an increased risk of fatal CHD and sudden cardiac death in addition to an increased risk of metabolic syndrome components and diabetes*. (FAO, 2010)* EU 2015 suggested a legal limit for **industrial** TFA content “*Reductions of TFA are targeted to industrially produced TFA because the proportion of TFA in those fats can be modified whereas the proportion of TFA in ruminant fats is relatively stable”….“Technically, ruminant TFA cannot be covered by this measure [i.e. legal limit] as TFA are formed naturally in relatively stable proportions in ruminant fats, and cannot be avoided in ruminant products, that contribute essential nutrients in the EU diet”.*

Milk fat, inherent in milk, serves as an important delivery medium for fat soluble vitamins, various fatty acids and factors beneficial to health – components that will be naturally present in the formula as a result of the milk base. TFA is naturally present in milk. Typical TFA values (measured as C18:1) in bovine milk fat, range from 1.29 to 7.31% of total fat (Precht et al, 2000, review of milk fat from >12 countries). Breast milk contains also contains TFA ( 2-5% of total FA) (Larqué et al 2001). * Analysis of the TFA content in milkfat by Precht and Molkentin (2000) from >12 countries shows that average TFA levels range from 1.3- 5.53% with upper values of 7.89%. The proportion of TFA as a % of total fat in milkfat and milk is consistent.
* Kliem et al (2013) in a survey of five English supermarkets for 12 months showed that the monthly average monounsaturated trans fatty acid content  of the milk ranged from 3.78 to 5.46% of the total fatty acids, while the total trans fatty acids (less CLA) ranged from 4.30 to 5.88% of total fatty acids, with the individual averages higher This was consistent with the data published by others including (Heck, van Valenburg, Dijkstra & van Hooijdonk, 2009; Lock & Garnsworthy, 2003: IN Kliem et al 2013)
* Aro et al (1998) analysed the TFA content of milk from 14 European Countries. The average ranges from  3.19-5.09% trans of total fatty acids.

A TFA maximum level aligned with the IF Std (3%) does not allow for milkfat to form the predominant fat in 12-36mo formula. The historical rationale to include a limit of 3% TFA in the infant formula standard was to allow for natural levels in milkfat. However, as outlined by the eWG, higher average levels of TFA in milkfat have since been reported. YCF should allow a higher proportion of dairy fat than the IF Std and hence allow products formulated principally on milk within scope, also therefore reflecting dietary guidelines to consume full fat milk. Reference:Uauy R et al., (2009) Review.  WHO Scientific update on trans fatty acids: summary and conclusions.  EJCN 63, S68-75.FAO (2010) Food and Nutrition Paper 91.  Fats and fatty acids in human nutrition.  Report of an expert consultation.  (<http://foris.fao.org/preview/25553-ece4cb94ac52f9a25af77ca5cfba7a8c.pdf>, accessed 5 July 2016)De Souza, R.J. 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. BMJ. 351:h3978Colon-Ramos U, Baylin A, Campos H. The relation between trans fatty acid levels and increased risk of myocardial infarction does not hold at lower levels of trans fatty acids in the Costa Rican food supply. *J**Nutr* 2006;136:2887-92.Baylin A, Kabagambe EK, Ascherio A, Spiegelman D, Campos H. High 18:2 trans-fatty acids in adipose tissue are associated with increased risk of nonfatal acute myocardial infarction in costa rican adults. *J Nutr* 2003;133:1186-91.Block RC, Harris WS, Reid KJ, Spertus JA. Omega-6 and trans fatty acids in blood cell membranes: a risk factor for acute coronary syndromes? *Am Heart J* 2008;156:1117-23.Ghahremanpour F, Firoozrai M, Darabi M, Zavarei A, Mohebbi A. Adipose tissue trans fatty acids and risk of coronary artery disease: a case-control study. *Ann Nutr Metab* 2008;52:24-8.Park Y, Lim J, Lee J, Kim S-G. Erythrocyte fatty acid profiles can predict acute non-fatal myocardial infarction. *Br J Nutr* 2009;102:1355-61.Van de Vijver LP, van Poppel G, van Houwelingen A, Kruyssen DA, Hornstra G. Trans unsaturated fatty acids in plasma phospholipids and coronary heart disease: a case-control study. *Atherosclerosis*1996;126:155-61.Aro A, Kardinaal AF, Salminen I, et al. Adipose tissue isomeric trans fatty acids and risk of myocardial infarction in nine countries: the EURAMIC study. *Lancet* 1995;345:273-8.Stender, S. et al. 2008. Ruminant and industrially produced trans fatty acids: health aspects. Food & Nutrition Research. DOI: 10.3402/fnr.v52i0.1651Fardet A, Boirie Y. Associations between food and beverage groups and major diet-related chronic diseases: an exhaustive review of pooled/meta-analyses and systematic reviews. Nutr Rev 2014;72: 741–62.Praagman J, Franco OH, Ikram MA, Soedamah-Muthu SS, Engberink MF, van Rooij FJ, Hofman A, Geleijnse JM. Dairy products and the risk of stroke and coronary heart disease: the Rotterdam Study. Eur J Nutr 2015;54:981–90.Department of Health and Human Services Fed Regist 2015;148832013: 34650-70  |

**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:*IDF do not support establishing a minimum carbohydrate level. Carbohydrate, specifically lactose, is naturally present in the product as it is inherent in key cow’s ingredients.  |
| If you support establishing a minimum available carbohydrates level, what level do you support? |
| ☐ Full fat cows’ milk 7.5 mg/100 kcal 1.8 mg/100 kJ | ☐ IEG 2015 and proposed Codex FUF-OI 9.0 mg/100 kcal 2.2 mg/100 kJ |
| *Please provide your rationale:*n/a |
| 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:*IDF supports establishing a maximum for total carbohydrates. Rationale is outlined below. In setting a maximum, the inherent carbohydrate content (lactose) of the core base milk ingredient will need to be accounted for.  |
| 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:*A limit should be set for total CHO, in order to restrict added sugars and/or added refined carbohydrate ingredients that can have a high GI (in some cases above 100), while providing little or no other nutrients and result in YCF with a GI significantly greater than the cow’s milk beverages such products typically substitute in the diet. Ingredient combinations (& resulting ingredient proportions by weight) that could be used to deliver the defined macronutrient ranges must be considered when setting a CHO cap. Reduced protein formulations could result in a high added carbohydrate ingredient addition ( >50% added CHO by weight) when formulated at the lowest minimum fat level. IDF suggests consideration be given to a total CHO cap of less than 14g/100kcal, and that this should be defined after minimum protein levels are set. Liquid whole milk has a GI of approximately 30 (Ref). Added sugars and largely refined, hydrolysed carbohydrate sources can significantly impact ~~on~~ the GI of YCF and their insulin response (Brand-Miller et al. 2012). Consuming foods with high GI has been associated with cardiometabolic risk (Mozaffarian 2016). Consumption of diets with a low glycaemic index reduced total cholesterol and LDL cholesterol as compared with diets with a high glycaemic index (Ref), and may be linked to increased risk of obesity (Hauer et al. 2012). As well as inducing a higher glycaemic response, these types of CHO may also be less satiating than protein, and may lead to an overall increase in energy intakes. Protein is the most satiating of all macronutrients, i.e. more satiating than carbohydrates and fat (Benelam 2009). Dietary recommendations generally emphasise that the source of carbohydrates should be healthy carbohydrates (e.g. wholegrain products), while refined carbohydrates should be limited. This recommendation would also apply to young children – there is no reason to believe that refined carbohydrates would be more beneficial for young children than for adults.Lactose is the least cariogenic of all mono- and disaccharides (Brudevold 1983; Moynihan 2002; Bowen 2005), has the lowest GI after fructose, and is the natural CHO/ sugar present in breast milk and the cow’s milk base of YCF. As such, it should be the preferred carbohydrate source in YCF. IDF suggests that >50% of carbohydrate should be from lactose. Furthermore, we suggest restriction of free sugars (as defined by WHO) to less than 10% of total energy. ReferencesBenelam B (2009) Satiation, satiety and their effects on eating behaviour. Nutrition Bulletin 34:126-173.Brand-Miller et al. (2013) Effect of added carbohydrates on glycemic and insulin responses to children’s milk products. Nutrients 5:23-31. Hauer et al. (2012) Evidence-based guideline of the German Nutrition Society: carbohydrate intake and prevention of nutrition-related diseases. Ann Nutr Metab 60(Suppl 1):1.58.Mozaffarian (2016).\_Dietary and policy priorities for cardiovascular disease, diabetes, and obesity. A comprehensive review. Circulation 133:187-225.Goff LM, Cowland DE, Hooper L, Frost GS. Low glycaemic index diets and blood lipids: a systematic review and meta-analysis of randomised controlled trials. Nutr Metab Cardiovasc Dis. 2013;23(1):1–10 (http://www.ncbi.nlm.nih.gov/pubmed/22841185, accessed 2 November 2015).Stephen (2012). The role and requirements of digestible dietary carbohydrates in infants and toddlers. European Journal of Clinical Nutrition 66, 765 – 779. |
| If you support establishing a maximum/GUL, do you support 14 g/100 kcal (3.3 mg/100 kJ)? |
| ☐ Yes | ☒ No (please specify your alternative). |
| *Please provide your rationale:*IDF considers a maximum lower than 14g/100kcal could be appropriate and notes whole and reduced fat (1.5%) milk which has been used to guide the proposed energy density and fat range, has average CHO significantly less than the proposed level (7.2g/100kcal, 10.4g/100kcal, respectively). |

|  |
| --- |
| **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 StandardSucrose 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 2015Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content | ☐ An alternative level (please specify) |
| *Other permitted carbohydrates* |
| ☐ Proposed Codex FUF‑OI StandardOnly 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)*As per our definition of excluded carbohydrates to the WHO definition of added sugars* |
| *Please provide your rationale:* |

**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** mg/100 kcalmg/100 kJ | **Minimum**1.0[0.25] | **Maximum**[2.0][0.3] | **GUL**[3.0][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:* |
| 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:* |
| Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae? |
| ☐ | Yes | ☐ | No |
| *Please provide your rationale:*  |
| 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:* |

**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 kcalmg/100 kJ | **Minimum**[50] [90] [200][18] [22] [24] [48] | **Maximum**[N.S.] | **GUL**[180] [NS][43]  |
| **Minimum:** |
| ☐ Current Codex FUF standard90 mg/100 kcal22 mg/100 kJ | ☐ Proposed Codex FUF standard for older infants 50 mg/100 kcal12 mg/100 kJ |
| ☐ IEG 2015200 mg/100 kcal | ☐ Alternative value, please specify |
| *Please provide justification for your answers.*IDF considers calcium, riboflavin and vitamin B12 should be included as mandatory nutrients in YCF because they are essential nutrients for which milk is a major contributor to young children’s diets. Therefore, the proposed minimum levels should be referenced to minimum levels found in cow’s milk, with additional adjustment as formulations will always target levels greater than the minimum to ensure compliance.Average calcium levels of whole cow’s milk are 112mg/100g (with a range 91-120mg/100g).This equates to an average calcium density of 180mg/100kcal with a range of 146mg – 193mg/100kcal.), when converted using an average energy density of 62kcal/100mL (FAO, 2013).  |
| **Maximum/GUL:**  |
| ☐ Current Codex FUF standardMaximum: N.S. | ☐ Proposed Codex FUF standard for older infants GUL: 180 mg/100 kcalGUL: 43 mg/ 100 kJ |
| ☒ IEG 2015GUL: N.S.IDF does not consider an upper limit is justified for Calcium on the basis of the wide range (>5 fold difference) between NRV and UL, and therefore very low likelihood of excess intakes. | ☐ Alternative value, please specify |

|  |
| --- |
| **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:*Not necessary. The most important factor to address the potential adverse effects of high phosphorus intakes is to ensure adequate calcium intakes throughout life. As long as calcium intake is at adequate levels, phosphorus has little impact on bone health.  |

**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 µg RE/100 kcalµg RE/100 kJ | Minimum[75] [60] [50][18] [14] [12] | Maximum[225] [180] [54] [43] | GUL[200] [180][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:*IDF supports mandating vitamin A and considers it important that vitamin A levels are not lower than that found in whole milk. IDF notes the levels proposed by the IEG at 60ug/100kcal are comparable to the average levels of vitamin A in whole milk (58ug/100kcal, calculated from FAO, 2013).  |
| **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:* |
| **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:* |
| 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:*Inadequate vitamin D intake is prevalent around the world. Milk is an efficient vehicle for delivering several critical micronutrients and as such many countries have vitamin D fortification policies. Therefore IDF would not oppose mandatory addition of vitamin D. |
| 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:* |

**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:*IDF notes the minimum levels suggested by the IEG at 0.6ug/100kcal, are comparable to the average levels of zinc found in whole milk (0.6ug/100kcal as calculated from FAO, 2013). IDF does not recommend a specific level; however, suggests the minimum zinc levels recommended in the Standard are not lower than minimum levels found in whole milk. |
| 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:* |

**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. |

**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:*IDF considers that minimum B12 levels in the YCF product should be guided by minimum levels in whole milk. As outlined by the eWG, whole cow’s milk contains an average vitamin B12 level of 0.8ug/100kcal (0.4-1.4ug/100kcal as calculated by the eWG Chair) with reduced fat milk containing higher levels. Dietary surveys indicate that milk is a significant contributor to a young child’s B12 intake (Ref). B12 intake from milk is particularly important for those children consuming a predominantly plant-based diet. As outlined also for calcium and riboflavin, proposed minimum levels of this nutrient in the Standard should be referenced on minimum levels found in whole milk.  |
| 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:*In the absence of a Upper Limit for B12, IDF does not consider a GUL or a Maximum necessary i.e. IDF supports N.S. |

**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:* IDF notes the average levels of riboflavin in cow’s milk: 0.20mg/100g (range 0.17-0.20mg/100g, which calculates as 0.27mg – 0.32mg/100kcal (converted with 62kcal) (FAO, 2013).Similar to the rationale outlined for calcium and B12, IDF notes milk is a major contributor to young children’s dietary intakes of this nutrient. As YCF has been shown to be used as a substitute for milk (Alexy & Kersting, 2003) in the diet, it is important this nutrient is mandated.  |
| 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:*In the absence of a UL for riboflavin, IDF does not suggest that a GUL or maximum is necessary i.e. IDF supports N.S.. |

**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:*No – low levels are inherent in the dairy ingredients, it is not necessary to mandate a minimum level in the context of this complementary food which is consumed as part of a mixed diet. The ingredients used in YCF do not pose risk of delivering excess sodium. |
| 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:**No*  |

**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.* |
| Are there any labelling areas where different provisions may be required for the two age groups?  |
| *Please provide justification for your answer.* |
| 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:* |
| 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:* |
| 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:* |
| 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:* |