CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4a **CX/NFSDU 18/40/4-Rev**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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26 – 30 November 2018

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA: ESSENTIAL COMPOSITION REQUIREMENTS
Comments at Step 6 (Replies to CL 2018/62/OCS-NFSDU)

Comments of Australia, Brazil, Canada, Colombia, Indonesia, Japan, New Zealand, Norway, Peru, Philippines, Switzerland, United States of America, AOCS, EU Specialty Food Ingredients, EUVEPRO and ISDI

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/62/OCS-NFSDU issued in July 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER
For consistency, Australia suggests use of two significant figures for nutrient limits, and consistent application of the conversion factor of 4.18 when converting nutrient levels between kcal and kJ. Specific proposals are made below.	**Australia**
New Zealand comments on SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS Comment 1: New Zealand notes that throughout Section A both 'follow-up formula' and 'follow-up formula for older infants' are used when referring to the product. We consider it important to be explicit about which product is being referred to and spell out the agreed product name in full 'follow-up formula for older infants' each time in order to avoid any misunderstanding. We note this is currently not done consistently, particularly in the footnotes. Comment 2: New Zealand notes that clause 3.1.1 refers to footnote 1 but this footnote is missing from the Standard: 3.1.1 Follow-up Formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL) 1 as appropriate. The footnote should be adopted from the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981), with 'infant formula' replaced with 'follow-up formula for older infants'. Footnote 1 would thus be: Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in follow-up formula for older infants should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-up formula for older infants or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs. Comment 3: New Zealand considers that in footnote 9 'cow's' should be deleted as lactose and glucose polymers are the preferred carbohydrates irrespective of which animal milk is used. We also note that in Section B [name of product] for young children 'milk protein' is used so the deletion of 'cow's' in footnote 9 for follow-up formula for older infants would be consistent with that: c) Carbohydrates Available carbohydrates 9) Unit Minimum Maximum GUL g/100 kcal 9.0 14.0 - g/100 kJ 2.2 3.3 - 9) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cow's milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. 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. New Zealand comments on SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN Comment 1:	**New Zealand**

New Zealand notes that within 3.1.1 an asterisk is used whereas all other footnotes are given a number. New Zealand considers that the footnote to 3.1.1 should be given the number 1 and all subsequent footnotes be re-numbered:

3.1.1 (Name of product) for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)□, as appropriate. The general principles for establishing these levels are identified in Annex I of this standard.

Comment 2:
New Zealand does not agree with the following text currently in square brackets within footnote 4:

a) Carbohydrates			
Available carbohydrates 4)			
Unit	Minimum	Maximum5)	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

4) [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.
Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]

New Zealand proposes the following footnote:
[Lactose should be the preferred carbohydrate in [name of product] based on milk protein.

All sources of mono- and disaccharides, other than lactose, should not exceed 2.5 g/100 kcal (0.60 g/100 kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.]

Rationale
New Zealand does not consider that a specific sentence for products not based on milk protein is needed as the footnote as a whole restricts the use of mono- and disaccharides and there is a limit for total available carbohydrates. New Zealand does not support reference to sweet taste as this is challenging to measure and enforce.

New Zealand is of the view that the proposed footnote is unnecessarily long and considers that ‘all sources of mono- and disaccharides’ would capture the current wording of ‘ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means’.

New Zealand does not support any reference to non-carbohydrate ingredients within this footnote and considers that restrictions for the addition of these ingredients should be covered elsewhere in the Standard. We note that the Section on Food Additives in the current standard does not permit the addition of sweeteners. If it was considered important to specify that sweeteners are not permitted, this could

be included in the Food Additives section. Comment 3: New Zealand agrees with the mandatory addition of vitamin D to [name of product] for young children and supports the adoption of the values in the square brackets. We do not support the heading referring only to vitamin D3. Both forms of vitamin D are permitted for infant formula and follow up formula in the list of the permitted forms of nutrients in the Codex Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979). As such, it is was intentionally proposed to refer to vitamin D in the requirements for follow-up formula for older infants (CX/NFSDU 15/37/5) and this should also apply to [name of product] for young children. New Zealand agrees with footnote 9 and supports the adoption of the text in the square brackets: [Vitamin D39)] Unit Minimum Maximum GUL µg10) /100 kcal [1.5] [4.5] - µg10) /100 kJ [0.36] [1.08] - [9) Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.] 10) Calciferol. 1 µg calciferol = 40 IU vitamin D. Comment 4 New Zealand considers that 'or nutrients' within clauses 3.2.1 and 3.2.2 should be deleted as the clauses are otherwise in conflict with clause 3.2.3 which specifically covers the addition of additional nutrients. Additional nutrients should be permitted within the range specified for follow-up formula for older infants taking into account any inherent levels of nutrients in cow's milk as is indicated in clause 3.2.3: 3.2 Optional Ingredients 3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, or substances or nutrients may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted. 3.2.2 When any of these ingredients, or substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect. 3.2.3 Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation. Additionally, New Zealand has the following editorial comment on clause 3.2.2: - 'formula' should be replaced with 'product' for consistency in terminology	
Several of the proposed minimum and maximum requirements for nutrients deviate from Norwegian legislation, which is based on the recent scientific opinion of EFSA	**Norway**

The Philippines supports the Essential Composition of the Review of the Codex Standards for Follow Up Formula. This has been consistent with the outcome of the electronic working group and consensus of the previous Committee Session as justified by generally accepted scientific evidence. These are also in line with the previous Philippine Positions.	**Philippines**
Para 59: maximum level of vitamin A: The U.S. continues to support the maximum level of 180 µg RE/100 kcal for vitamin A. This vitamin A level allows for flexibility to address the needs of the target population and is not a required level to achieve. Norway raised a concern regarding the level of preformed vitamin A in Part B of the Standard because children aged between 12 and 36 months receive vitamin A from a progressively diversified diet in addition to that contained in follow-up formula; thus, a maximum of 180 µg (retinol equivalents per 100 kcal) may be too high and could lead to intake exceeding the upper tolerable level (UL). The UL does not apply to vitamin A derived from carotenoids. We note that the UL is not without some controversy because of limitations to the data on which it is based . We acknowledge Norway's concern and note that vitamin A deficiency is relatively rare in European countries, the USA, and Canada. However, Vitamin A deficiency is a major nutritional problem for 12-36-month old young children in resource-constrained countries, particularly the Philippines, Mexico and Brazil and some subgroups of the population in Indonesia. The UL is not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient. Thus, the Committee identified inclusion of vitamin A level in the product for young children 12-36 months as a mandatory ingredient since deficiency of vitamin A is a major nutritional problem for this age group in resource-constrained countries. The Committee decided on a lower maximum of 180 µg RE/100 kcal for the 12-36-month-old product rather that the level in the current FUF Standard of 225 µg RE/100 kcal to avoid the risk of toxicity. To address potential toxicity concerns, modeling was provided by eWG chairs provided the committee for the basis for the maximum vitamin A level as follows: Using a daily intake range of 300 – 500 ml of follow-up formula for young children, and an energy density of 65 kcal/100 mL (mid-point of the proposed energy density range), this would provide 350 - 585 µg of vitamin A (modelling 180 RE µg/100 kcal). The UL for vitamin A for 12-36 month old children is 600 µg of vitamin A per day . Intervention programs should be taken into consideration when determining the level of vitamin A that would be suitable in the 12-36 month old product. Paras 60-62: The United States supports adoption of the "essential composition requirements for older infants and young children" of the standard at Step 5 to progress the diligent efforts of the eWG chairs, eWG and CCNFSDU. At CCNFSDU37, the Committee agreed to the approach and key themes for the essential composition of follow-up formula for young children (12-36 months) as outlined in CX/NFSDU 15/37/5 (section 8). The eWG has been tasked with reviewing the compositional requirements of follow-up formula for young children based on discussions at CCNFSDU37 and the approach outlined in CX/NFSDU 15/37/5. To provide for appropriate consideration of whether of the structure of this standard, the Committee agreed to determine the composition of the products with a demarcation at 12 months of age. By determining the nutrient composition of the product for the 12-36-month-old first, addressing the different uses of the product category based on the age of the intended consumer to prevent misuse or misrepresentation of the product could be considered logically.	**USA**
Acceptable	**AOCS - American Oil Chemists' Society**

1. We welcome the adoption at Step 5 of the essential compositional criteria of the standard at CAC41 in July 2018, an important step in the advancement of the standard. The recognition of the differentiation in requirements between formula for older infants (6-12 months) and [name of the product] for young children (12-36 months) is also supported, reflecting the different roles of these products as part of a diversified diet, and which are a good source of nutrition for both macro and micronutrients. 2. We therefore strongly encourage Codex national delegations to re-iterate their support for the essential composition requirements at Step 6 and in view of continued consideration of the standard at CCNFSDU40 in November 2018. 3. In addition, we would like to stress the importance of vitamin D for young children and re-iterate our support for the minimum value of 1.5 µg/100 kcal and maximum value of 4.5 µg/100 kcal for [NAME OF PRODUCT] FOR YOUNG CHILDREN which are in line with the recommendations expressed by the International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition (Suthutvoravut et al., 2015). Vitamin D is not only important for avoiding rickets. More and more data demonstrate its key role in a multiple of metabolic pathways and functions from muscle strength to immunity. Many publications show that the prevalence of vitamin D deficiency is high, not only in countries with low sun but also in sunny countries. In tropical or subtropical climes, there is generally abundant exposure to sunlight, but vitamin D deficiency may arise in association with risk factors such as darker skin pigmentation, atmospheric pollution, and covering skin for religious or cultural reasons (Baroncelli, Bereket et al. 2008, Elder and Bishop 2014, Green, Samy et al. 2015, Trilok Kumar, Chugh et al. 2015). Studies on vitamin D levels in infants and children in sub-Saharan Africa are somewhat limited (Wahl, Cooper et al. 2012, Hilger, Friedel et al. 2014), but the available evidence indicates that despite the high level of sunshine, both vitamin D deficiency and vitamin D dependent rickets are an issue in infants and children: A study in children aged 2 years and younger from Botswana found that nearly 20% were vitamin D deficient (Ludmir, Mazhani et al. 2016). Nutritional rickets remains a serious public health issue, and while in West Africa, its main cause seems to be inadequate calcium intakes, vitamin D deficiency plays an important role in countries such as Kenya, Congo and Malawi (Creo, Thacher et al. 2017) and low vitamin D levels seem to be an independent risk factor even in a sub-Saharan context (Jones, Hachmeister et al. 2018). It has been shown that children in poor urban settings in Kenya often only had less than 3 hours of sun exposure, which increased their risk of inadequate vitamin D levels and rickets (Edwards, Thiongó et al. 2014). A further study in Kenya showed that as many as 75% of infants had insufficient vitamin D levels at birth (Toko, Sumba et al. 2016). Particularly in urban settings, sun exposure can at times be very low (Creo, Thacher et al. 2017), while people with more traditional African lifestyles tend to have 25-OH levels at the upper end of the spectrum (Luxwolda, Kuipers et al. 2012). However, these do not seem to be associated with adverse health outcomes in the specific context. Correcting vitamin D deficiency might be particularly important in this area as there is some evidence that it might be associated with the severity of malaria (Cusick, Opoka et al. 2014).	**EU Specialty Food Ingredients**
ISDI recommends consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The	**International Special**

changes needed to achieve this are noted as technical changes for each specific paragraph in the document where changes are needed to achieve this, and these minor changes make up the majority of the changes sought. Please note that ISDI considers the following two exceptions do not need to be amended as they align with the approach used in the Codex Infant Formula Standard: 1) Energy limits in kJ rounded to nearest 5, and, 2) Maximum carbohydrate levels per 100 kcal stated to 3 significant figures.	**Dietary Food Industries**

Text	**MEMBER / OBSERVER AND RATIONALE**
SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS **3 ESSENTIAL COMPOSITION AND QUALITY FACTORS** **3.1 Essential composition**	
3.1.3 Follow-up Formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL) [1] as appropriate.	
	International Special Dietary Food Industries ISDI notes that an explanation of GULs has been included in Section B but not in Section A. ISDI recommends that a consistent approach is used and an explanation is included in both sections.
[2)]For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.	
	Indonesia Indonesia proposes to add conversion factor of 5.71 for soybean protein isolates use in Standard of Follow-Up Formula for Older Infants. Rationale : - To be in line with Codex Stan 72-1981 - Based on FAO document (http://www.fao.org/uploads/media/FAO_2003_Food_Energy_02.pdf)
[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 of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)); 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.	
Indonesia proposes to add ratio for methionine:cysteine in follow-up formula for older infant.	**Indonesia** Rationale : For amino acid balance
For an equivalent energy value, ... However, for the	**Peru**

purpose of the calculation, the concentrations of tyrosine and phenylalanine and the concentrations of methionine and~~systeine~~ cysteine can be added.	
For an equivalent energy value, ... However, for the purpose of the calculation, the concentrations of tyrosine and phenylalanine and the concentrations of methionine and~~systeine~~ cysteine can be added.	**Colombia** Colombia proposes that the correct Spanish translation of cysteine [cisteína] be used.
[6] A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.	
	Australia Australia supports changes to footnote 6. The amended footnote allows protein minimum levels between 1.6 – 1.8 g/100 kcal to be established as safe and suitable for infants following scientific evaluation by competent national and/or regional authorities in the context of the nutritional needs of their local population. This approach provides flexibility for countries to consider whether to permit protein levels below 1.8 g/ 100 kcal based on their own scientific evaluation of the evidence.
	Philippines The Philippines supports Footnote "6 A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula based on non-hydrolysed milk protein can be accepted. Such follow up formula and follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal (0.54 g/100 kJ) should be evaluated for their safety and suitability, and assessed by a competent national and/or regional authority based on clinical evidence."
[6] A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula based on non-hydrolysed milk protein can be accepted. Such follow-up formula ~~and follow-up formula based on hydrolysed protein~~ should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence~~.~~**. Follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal (0.54 g/100 kJ) should be scientifically substantiated, clinically evaluated when needed, and assessed by a competent national and/or regional authority who may deviate from this threshold as appropriate.**	**International Special Dietary Food Industries** ISDI recommends that this wording is reviewed with respect to follow-up formula based on hydrolysed protein, maintaining its position (i.e. retention of 2.25 g/100kcal) submitted for the CCNFSDU39 agenda paper. The approach to evaluate follow-up formula based on hydrolysed protein, containing less than 2.25 g protein/100 kcal, is aligned with the infant formula standard. It is not logical to implement stricter requirements for this older age group (6-12 months). A last sentence is proposed to give competent authority flexibility to deviate from this threshold. Hydrolysed protein has been safely used as a protein source in follow-up formula for older infants. Several studies have demonstrated that formulas based on hydrolysed protein support adequate growth of during infancy.

	References Berseth CL, Mitmesser SH, Ziegler EE, et al. Tolerance of a standard intact protein formula versus a partially hydrolyzed formula in healthy, term infants. Nutrition Journal. 2009. June 19;8:27. EFSA. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1.9 g protein/100 kcal. EFSA Journal 2005; 280: 1-16. Sauser J, Nutten S, de Groot N, Pecquet S, Simon D, Simon HU, Spergel JM, Koletzko S, Blanchard C. Partially Hydrolyzed Whey Infant Formula: Literature Review on Effects on Growth and the Risk of Developing Atopic Dermatitis in Infants from the General Population. Int Arch Allergy Immunol. 2018 Jul 12:1-12. Scalabrin DM, Johnston WH, Hoffman DR, et al. Growth and tolerance of health term infants receiving hydrolyzed infant formulas supplemented with Lactobacillus rhamnosus GG: randomized, double-blind, controlled trail. Clin Pediatr (Phila) 2009; 48: 734-44. Vandenplas Y, Alarcon P, Fleischer D, et al. Should partial hydrolysates be used as starter infant formula? A working group consensus. Journal of Pediatric Gastroenterology and Nutrition, 2016 Jan;62(1): 22–35 Ziegler EE, Jeter JM, Drulis JM, Nelson SE, Haschke F, Steenhout P, Brown C, Maire J-C, Hager C. Formula with reduced content of improved, partially hydrolyzed protein and probiotics: infant growth and health. Monatsschr Kinderheild 2003; 151: S65-S71. 'Clinically evaluated when needed' takes the following into consideration: o the effect of feeding a formula manufactured from protein hydrolysate on growth; is best evaluated when the formula is provided as sole-source nutrition (i.e. infant formula). Therefore, when the safety & suitability of an infant formula manufactured from protein hydrolysate has been scientifically substantiated; there should be no requirement to substantiate the safety and suitability of the protein hydrolysate in follow-on formula for use in older infants. 2. o as a wider body of evidence becomes available, clinical evaluation may become redundant 'Scientifically substantiated' addresses the fact that data, other than clinical data, are also important.
b) Lipids	
	Indonesia Indonesia supports the proposed minimum and maximum level for total fat.
[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk	

fat in infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kCal (72 mg/100 kJ).	
[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in ~~infant formulae~~Follow-up formula for older. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).	**Australia** The third sentence in 3.1.3 footnote 8 contains an error. The text currently references infant formulae and needs to be amended to 'Follow-up formula for older infants'.
[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in ~~infant formulae~~follow up formula for older infant. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).	**Indonesia**
[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in ~~infant formulae~~follow up formula. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).	**Philippines**
[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in ~~infant formulae~~follow-up formula(e) for older infants. The erucic acid content	**International Special Dietary Food Industries** While this text is sourced from the Codex infant formula standard, the product name needs to amended from 'infant formulae' to 'Follow-up formula(e) for older infants.'

shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).	
Linoleic acid GUL: 335mg /100 kJ	
~~335~~330	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kJ should be revised accordingly.
c) Carbohydrates	
[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cow's milk protein and hydrolysed protein. Only the precooked and/or gelatinised starches gluten-free by nature may be added. 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	
[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cow's milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be ~~added~~added with the sum of these does not exceed 30% of available carbohydrate. 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.	**Indonesia**
[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on ~~cow's~~ milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. 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.	**Philippines**
[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on ~~cow's~~ milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. 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.	**International Special Dietary Food Industries** ISDI recommends that cow's milk is deleted and the wording does not specify the specific type(s) of milk protein since, lactose and glucose polymers are the preferred carbohydrates irrespective of which animal milk protein used.
d) Vitamins	

Vitamin A	
	Norway As we previously expressed, we are concerned about a maximum value of 180 µg RE vitamin A/100 kcal, since it can lead to overexposure of vitamin A. EFSA has stated that children are particularly sensitive to excessive vitamin A intakes (EFSA 2014). Therefore, we would support a lower Codex value of 114 µg RE vitamin A/100 kcal.
Vitamin D	
Vitamin ~~D~~D3	**Colombia** Colombia proposes that it be specified that the accepted form of vitamin D is D3, as specified in Section B of the preliminary draft.
11) Calciferol. 1 µg calciferol = 40 IU vitamin D.	
	Peru The opinion of the National Technical Committee in the framework of the Codex Alimentarius with respect to the document CL 2018/62/OCS-NFSDU is to be in agreement with the document.
11) ~~Calciferol~~cholecalciferol. 1 µg of ~~calciferol~~ cholecalciferol = 40 UI of vitamin D.	**Peru**
Vitamin E **Unit** **Minimum** **Maximum** **GUL** mg α-TE12) /100 kcal 0.5 13) - 5 mg α-TE12) /100 kJ 0.12 13) - 1.2	
Minimum	
0.~~5~~ 50 13)	**Australia**
0.~~5~~ 50 13)	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum and the GUL per 100kcal should be revised accordingly.
GUL	
5.0	**Australia**
5.0	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum and the GUL per 100kcal should be revised accordingly.

Vitamin K **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 4 - 27 µg /100 kJ 1.0 - 6.5	
Minimum	
4.0	**Australia**
4.0	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kcal should be revised accordingly.
GUL	
27.0	**Australia**
Riboflavin **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 80 - 500 µg /100 kJ 19 - 119	
GUL	
~~119~~120	**Australia**
~~119~~120	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kJ should be revised accordingly.
Vitamin B_6 **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 35 - 175 µg /100 kJ 8.4 - 41.8	
GUL: 175µg /100 kcal	
~~175~~180	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kcal and 100 kJ should be revised accordingly.

GUL: 41.8 µg /100 kJ	
~~41.8~~43	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kcal and 100 kJ should be revised accordingly.
Vitamin B_{12} **Minimum:** 0.1µg /100 kJ	
0.~~1~~10	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kcal should be revised accordingly.
Pantothenic acid **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 400 - 2000 µg /100 kJ 96 - 478	
GUL: 478µg /100 kJ	
~~478~~480	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kJ should be revised accordingly.
Biotin **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 1.5 - 10 µg /100 kJ 0.4 - 2.4	
Minimum	
0.~~4~~36	**Australia**
0.~~4~~36	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kJ should be revised accordingly.

<table>
<tr><td colspan="2">e) Minerals and Trace Elements</td></tr>
<tr><td colspan="2">Iron [17)]
[17)] For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36//100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mlg/100 kJ) applies.</td></tr>
<tr><td>[17)] For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.~~6~~ 60 mg/100 kJ) applies.</td><td>International Special Dietary Food Industries
ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ.

The maximum per 100 kJ should be revised accordingly.</td></tr>
<tr><td colspan="2">Phosphorus
Unit Minimum
mg /100 kJ 6</td></tr>
<tr><td>6.0</td><td>International Special Dietary Food Industries
ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ.

The minimum per 100 kJ should be revised accordingly.</td></tr>
<tr><td colspan="2">Ratio calcium/phosphorus</td></tr>
<tr><td></td><td>Australia
Australia supports the deletion as indicated as there is no need to establish a calcium-to-phosphorus ratio for a product that is a part of a mixed increasingly diversified diet providing phosphorus from other sources. We also note that phosphorus is not considered to be a key nutrient in cows’ milk; WHO/FAO have not established a dietary intake reference value for phosphorus and there is no evidence for phosphorus intake being inadequate.</td></tr>
<tr><td colspan="2">Magnesium
Unit Minimum Maximum GUL
mg /100 kcal 5 - 15
mg /100 kJ 1.2 - 3.6</td></tr>
<tr><td colspan="2">Minimum</td></tr>
<tr><td>5.0</td><td>Australia</td></tr>
<tr><td>5.0</td><td>International Special Dietary Food Industries
ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ.

The minimum per 100 kcal should be revised accordingly.</td></tr>
</table>

GUL	
15.0	**Australia**
Sodium **Unit** **Minimum** **Maximum** **GUL** mg /100 kcal 20 60 - mg /100 kJ 5 14 -	
Minimum	
~~5~~4.8	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kJ should be revised accordingly.
Iodine **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 10 - 60 µg /100 kJ 2.4 - 14.3	
	Norway As we previously expressed, we are concerned of a GUL value of 60 µg iodine/100 kcal, since it can lead to overexposure of iodine. Therefore, we would support a lower Codex value of 29 µg iodine/100 kcal.
GUL	
14~~.3~~	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kJ should be stated as 14 not 14.3ug/100 kJ to consistently apply use of 2 significant figures.
Selenium **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 2 - 9 µg /100 kJ 0.48 - 2.2	
Minimum	
2.0	**Australia**
2.0	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ.

	The minimum and GUL per 100kcal should be revised accordingly.
GUL	
9.0	**Australia**
9.0	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum and GUL per 100kcal should be revised accordingly.
Zinc [20)] **Unit** **Minimum** **Maximum** **GUL** mg /100 kcal 0.5 - 1.5 mg /100 kJ 0.12 - 0.36	
	Norway As we previously expressed, we are concerned of a GUL value of 1.5 mg zinc/100 kcal, since it can lead to overexposure of zinc. Therefore, we would support a lower Codex value of 1.0 mg zinc/100 kcal.
Minimum	
0.~~5~~50	**Australia**
0.~~5~~50	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kcal should be revised accordingly.
3.2 Optional Ingredients	
Taurine **Unit** **Minimum** **Maximum** **GUL** mg /100 kcal - 12 - mg /100 kJ - 3 -	
Maximum	
~~3~~2.9	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The maximum per 100kJ should be revised accordingly.

Total nucleotides Levels may need to be determined by national authorities	
The levels ~~may need to~~ could be determined by the national authorities.	**Colombia** Colombia suggests modifying the wording in Spanish of the proposed text for the total nucleotides to better clarify the recommendation of the standard with respect to the determinations by the national authorities.
Docosahexaenoic acid [21)] **Unit** **Minimum** **Maximum** **GUL** mg /100 kcal - - 30 mg /100 kJ - - 7.2 [21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and 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.	
	Australia Australia supports removal of the square brackets as indicated for the GUL of 30 mg/100 kcal (7.2 mg/100 kJ). We note this level is supported by data (Koletzko et al. 2008).
GUL: 30 mg/100 kcal	
~~30~~50	**Philippines** The issue was raised in 39th Session of CCNFSDU that the range between the minimum value of 20 mg/100kcal and the GUL of 30mg/100kcal poses challenges for manufacturers due to the limited range for compliance. In addition EFSA (2014) has recommended a maximum of 50 mg /100 kcal, based on the highest observed DHA concentrations in human milk. Therefore, we propose that GUL be 50mg/100kcal, to provide a wider range and to reduce the risk of non-compliance due to variability in content in raw materials, loss during processing and over product shelf-life and the variability in analytical results. Further, this level does not pose any safety concern.
~~30~~50	**International Special Dietary Food Industries** At CCNFSDU39, ISDI raised the fact that the range between the minimum of 20 mg/100kcal and the GUL of 30mg/100kcal poses challenges for manufacturers due to the narrowness of this range for compliance. In addition EFSA (2014) has recommended a maximum of 50 mg /100 kcal, based on the highest observed DHA concentrations in human milk. Therefore, ISDI requests that the GUL is set higher and recommends 50mg/100kcal, to provide a wider range to reduce the risk of non-compliance due to variability in content in raw materials, loss during processing and over product shelf-life and the variability in analytical results. This level does not pose any safety concern.
GUL: 7.2 mg/100kJ	
~~7.2~~12	**International Special Dietary Food Industries**

	At CCNFSDU39, ISDI raised the fact that the range between the minimum of 20 mg/100kcal and the GUL of 30mg/100kcal poses challenges for manufacturers due to the narrowness of this range for compliance. In addition EFSA (2014) has recommended a maximum of 50 mg /100 kcal, based on the highest observed DHA concentrations in human milk. Therefore, ISDI requests that the GUL is set higher and recommends 50mg/100kcal, to provide a wider range to reduce the risk of non-compliance due to variability in content in raw materials, loss during processing and over product shelf-life and the variability in analytical results. This level does not pose any safety concern.
[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, a minimum level of 13~~20~~ mg/100 kcal (3.1~~4.8~~mg/100 kJ)should be reached, and 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.	**Japan** Given that there are gaps in DHA intakes of older infants between countries/regions, more flexibility should be allowed in the voluntary addition of DHA for countries/regions that may have different needs. Footnote 21 in the current draft allows competent national and/or regional authorities to deviate from the minimum value of DHA as appropriate for the nutritional needs. However, Japan believes that the widest range of DHA levels should be set so that an adequate amount of DHA can be provided for older infants in different countries/regions based on the nutritional needs of their local population. This flexibility would be given by setting the lower minimum DHA level of 13 mg/100 kcal that is 0.3% fatty acids of the total minimum fatty acids (4.4 g/100 kcal) as originally proposed at CCNFSDU39.
	Australia For footnote 21, Australia supports the increased minimum of 20 mg/100kcal (4.8 mg/100 kJ) on the basis that when optional ingredients are added the levels should be effective.
L (+) lactic producing cultures	
	Norway We agree that the standard allows for the use of lactic acid-producing cultures during the production process for the purpose of producing lactic acid in the product, and strongly support that the acidified final formula should not contain significant amounts of viable lactic acid-producing bacteria, and any residual amounts in the final product of residues should not present any health risk. Furthermore, we agree with the proposed principles that safety and suitability should be scientifically demonstrated if lactic acid producing cultures are added with an aim of a beneficial physiological effect. We support that this should be done for the specific strains and at the level of use. However, as we previously expressed, we are of the opinion that safety and suitability is not to date fully demonstrated for the use of probiotics in follow-up formula.
SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN **3 ESSENTIAL COMPOSITION AND QUALITY FACTORS** **3.1 Essential composition**	
	Canada Canada supports the name ‘Formulated drink for young children’ for products under the FUF standard which are intended for young children aged 1-3 years.

	Canada reiterates its support for the name 'Formulated drink for young children' as stated previously in the response to Recommendation 37 of the Agenda Item 4 at CCNFSDU39. The reason for supporting this name is its structural similarity to the term 'follow-up formula for older infants' which helps to maintain clarity and uniformity within the FUF standard.
3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.	
When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than ~~70~~ 85 kcal (295 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.	**Indonesia** Rationale : Considering the higher energy requirement for young children.
* Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in [name of product] for young children should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of [name of product] for young children or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.	
	Philippines An explanation of GULs has been included in Section B but not in Section A. The Philippines seeks clarification for the non – inclusion of an explanation of GULs in Section A, and recommends that a consistent approach be used and an explanation be included in both sections.
Protein [1), 2)] **Unit** **Minimum** **Maximum** **GUL** g/100 kcal 1.8 - - g/100 kJ 0.43 - -	
	Indonesia Indonesia proposes to increase minimum level of protein to 3 g/100 kcal considering higher protein requirement for young children.
For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion	

factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.	
1)	**Indonesia** Indonesia proposes to add conversion factor of 5.71 for soybean protein isolates use in Standard for Follow-Up Formula for Older Infants. Rationale : - To be in line with Codex Stan 72-1981 - Based on FAO document (http://www.fao.org/uploads/media/FAO_2003_Food_Energy_02.pdf)
2) When determined by PER methodology, the quality of protein shall not be less than 85% of that of casein.	
	Australia Australia supports the requirements as drafted, including the changes to footnote 2 to clarify when the PER methodology is used to determine protein quality the relevant reference is 'no less than 85% of that of casein'.
	European Vegetable Protein Association Footnote 2: As re-drafted, the requirement: "the quality of protein shall not be less than 85% of that of casein", only applies "when determined by the PER methodology", i.e. it does not seem to apply when determined using other methodology (PDCAAS, for example). Is this the intention of the footnote?
The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.	
The protein quality shall be determined ~~provisionally~~ using the PER or ~~PDCAAS and~~ PDCAAS, or other methods that come available in the future.	**European Vegetable Protein Association** This sentence does not seem to make sense, as it is not possible to "provisionally" use methods that do not exist. Better wording would be: "the protein quality shall be determined using the PER or PDCAAS, or other methods that come available in the future".
b) Lipids 3)	
	Australia Australia supports the removal of square brackets as indicated on the proposed minimum level of 3.5 g/100kcal (0.84g/100kJ)
3) Partially hydrogenated oils and fats shall not be used in [name of product] for young children.	
Partially hydrogenated oils and fats shall not be used in [name of product] for young children. The content of trans fatty acids shall not exceed 3% of total fatty acids.	**Indonesia** Indonesia proposes to add the following words to footnote 3:
c) Carbohydrates **Available carbohydrates** 4)	

	Australia Australia supports the maximum level for available carbohydrates of 12.5g/100 kcal (3.0g/100 kJ) and the proposed new footnote 5 to indicate that for a product with a protein level below 3 g/ 100 kcal.
[4]) [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.	
[Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate ~~sources (like starch) that have no contribution to the sweet taste~~ sources. Sucrose and/or fructose should not be ~~preferred.~~added, unless needed as a carbohydrate source.	**Australia**
[Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.	**Australia** In regards to the text in square brackets for Footnote 4, Australia agrees that the inclusion of reference to sweet taste is challenging, as is not defined or enforceable. While there may be sensory methods available to evaluate relative sweetness this varies depending on the matrix and is subjective. There is no standardised method to measure sweetness, measurement is complex thus we support removal of the sentences which refer to 'sweet taste'. Restriction of added sugars/free sugars (excluding lactose) to a maximum of 20% of available carbohydrate results in a limit of 2.8 g/100 kcal based on a maximum available carbohydrate content of 14 g/100 kcal. This means that a serving of 200 mL providing the maximum permitted energy content of 70 kcal/100 mL will provide a maximum of 3.9 g of added/free sugars excluding lactose (i.e. less than one teaspoon). This restriction limits the addition of sugars with cariogenic properties and/or with relative sweetness higher than lactose such that end products will not be overly sweet. For clarity and to simplify language, Australia also suggests changes to the following sentence: "mono- and disaccharides other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means" to capture the total content from all sources
[Lactose should be the ~~preferred~~ main source of carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.	**Switzerland** Switzerland supports that lactose should be the main source of carbohydrates, as it is the case for all types of milk (cow milk, goat milk and breastmilk).
[Lactose should be the preferred carbohydrates in [name of product] based on milk protein. ~~For products not based on milk protein, carbohydrate sources (like~~	**International Special Dietary Food Industries** Noting that there is no request for comments at that stage on this topic which remains in square brackets and at step 3, ISDI is sharing its rationale ahead of CCNFSDU40.

~~starch) that have no contribution to the sweet taste should be preferred.~~	ISDI strongly supports the efforts by CCNFSDU to introduce requirements for carbohydrates in [Name of product] for young children. Specific requirements are proposed in footnote 4, which remains in square brackets for further discussion at CCNFSDU. In line with all requirements in a codex standard, it is critical that this footnote is both objective and enforceable, once transposed into regional/national legislation. In this regard, ISDI does not support any reference to 'sweet taste' in footnote 4, as the concept of 'sweet taste' is complex, subjective, and non-enforceable. More specifically: • The only methods currently available to measure 'sweetness' require human sensory panels. Such methods are not appropriate for compliance/enforcement purposes. They are highly dependent on factors including food matrix, blood sugar level at time of consumption and temperature of the food ingested. The possibility of establishing sensory panels for the targeted population (1-3 year olds) is also questionable. • From an analytical perspective, it would be very difficult to develop/validate an objective method (appropriate for compliance/enforcement purposes) to measure sweetness. Complicating this analysis would be the need to calibrate any instrumental or immunological based assay back to a human tester. • Following the EFSA public consultation on a draft protocol for the Scientific Opinion on dietary sugars, EFSA has noted that "Sweet taste", and the development of taste and food preferences in infants and children, are not endpoints for the assessment. Considering the above, ISDI believes the setting a maximum level of mono and di-saccharides (other than lactose) is the most appropriate approach for footnote 4. ISDI strongly supports the efforts by CCNFSDU to restrict the level of mono- and disaccharides from all sources other than lactose at 2.5 g/100 kcal of available carbohydrates. At this maximum level, 'mono and di saccharides other than lactose' would contribute 10% of the products total energy. This aligns with the WHO (2015) guideline which strongly recommends the adults and children reduce their daily intake of free sugars to less than 10% of their total energy intake. However, it is important to point out that that the WHO guideline is 'dietary-based' i.e. it applies to the whole diet and not to specific products. In any case the introduction of this additional restriction on 'mono and di saccharides other than lactose' for Name of Product] for young children, coupled with the introduction of a maximum level for available carbohydrates are all significant changes). ISDI would also like to note the following comments: 1) The text, "…either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means," is a very wordy way of stating 'total amount present'. ISDI recommends that the sentence is simplified and this wording is deleted accordingly. 2) The following sentence, "National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ)," should be deleted. ISDI doesn't support a restriction on mono- and disaccharides other than lactose at 1.25g/100 kcal of available carbohydrate. This restriction is inspired by the WHO guideline to limit free sugars to less than 5% of total energy intake, which is a conditional recommendation. In addition, and as stated above, the recommendation is intended to apply to the total diet rather than individual products. 3) To achieve palatability, sucrose and/or fructose may be needed in certain formulas for example those

	based on plant protein, hydrolysed protein or lactose free. ISDI reiterates that all requirements incorporated into the revised codex standard must be enforceable, once the codex standard is transposed into regional /national law. ISDI considers, in that perspective, that the limits set for 'sugars (mono- and disaccharides other than lactose)' and 'available carbohydrates' are clear criteria. They are sufficient and appropriate for public health and are enforceable as they can be analytically measured.
Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]	
~~Mono-~~ mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). ~~Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]~~	**Australia**
The total content of Mono- and ~~disaccharides~~disaccharides from all sources, other than lactose, ~~either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means,~~ should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ)~~.~~. Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. ~~Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]~~	**Australia**
	Canada

	Canada supports retaining the statement on carbohydrate content in products for young children as mentioned in footnote-4. Obesity is a growing health problem worldwide with high levels observed even among young children and in both developed and developing countries. Indeed, 39% of adults worldwide are overweight while 13% are obese (WHO 2018a). Childhood obesity is also increasing at an alarming rate and the majority of obese children live in developing countries. The seeds of obesity are sown in early childhood when the preference for sugar-rich sweet-tasting foods and drinks is established (WHO 2018b). Hence, it is imperative to discourage the use of high sugar and/or sweet-tasting products for young children as suggested by the proposed text in footnote-4 of the draft revision of the FUF standard. Refs: 1. World Health Organization (WHO). 2018a. Fact sheet on obesity and overweight. http://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight 2. World Health Organization (WHO). 2018b. Facts and figures on childhood obesity. http://www.who.int/end-childhood-obesity/facts/en/
Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 25% of available carbohydrate. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]	**Indonesia** Indonesia proposes additional requirement for Sucrose and/or fructose or other carbohydrates used in products
Mono- and disaccharides, other than lactose, and other carbohydrates contributing to the sweet taste, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. However, n~~National~~ ational and/or regional authorities may define a lower limit ~~this level to 1.25 g/100 kcal (0.30 g/100 kJ)~~. Sucrose	**Switzerland** 1st sentence: Switzerland supports that “other carbohydrates contributing to the sweet taste” should be included into the limitation. 2nd sentence: Switzerland supports that National and/or regional authorities should be able to limit the carbohydrates, other than lactose, that contribute to the sweet taste of [name of product] for young children to a lower but not defined limit.

and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]	
Mono- and disaccharides, other than lactose~~, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means,~~ should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. ~~National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ).~~ Sucrose and/or fructose should not be added, unless needed as a carbohydrate source i**n products such as [Name of Product] based on plant protein, hydrolysed protein or lactose free].**~~Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]~~	**International Special Dietary Food Industries** Noting that there is no request for comments at that stage on this topic which remains in square brackets and at step 3, ISDI is sharing its rationale ahead of CCNFSDU40 ISDI strongly supports the efforts by CCNFSDU to introduce requirements for carbohydrates in [Name of product] for young children. Specific requirements are proposed in footnote 4, which remains in square brackets for further discussion at CCNFSDU. In line with all requirements in a codex standard, it is critical that this footnote is both objective and enforceable, once transposed into regional/national legislation. In this regard, ISDI does not support any reference to 'sweet taste' in footnote 4, as the concept of 'sweet taste' is complex, subjective, and non-enforceable. More specifically: • The only methods currently available to measure 'sweetness' require human sensory panels. Such methods are not appropriate for compliance/enforcement purposes. They are highly dependent on factors including food matrix, blood sugar level at time of consumption and temperature of the food ingested. The possibility of establishing sensory panels for the targeted population (1-3 year olds) is also questionable. • From an analytical perspective, it would be very difficult to develop/validate an objective method (appropriate for compliance/enforcement purposes) to measure sweetness. Complicating this analysis would be the need to calibrate any instrumental or immunological based assay back to a human tester. • Following the EFSA public consultation on a draft protocol for the Scientific Opinion on dietary sugars, EFSA has noted that "Sweet taste", and the development of taste and food preferences in infants and children, are not endpoints for the assessment. Considering the above, ISDI believes the setting a maximum level of mono and di-saccharides (other than lactose) is the most appropriate approach for footnote 4. ISDI strongly supports the efforts by CCNFSDU to restrict the level of mono- and disaccharides from all sources other than lactose at 2.5 g/100 kcal of available carbohydrates. At this maximum level, 'mono and di saccharides other than lactose' would contribute 10% of the products total energy. This aligns with the WHO (2015) guideline which strongly recommends the adults and children reduce their daily intake of free sugars to less than 10% of their total energy intake. However, it is important to point out that that the WHO guideline is 'dietary-based' i.e. it applies to the whole diet and not to specific products. In any case the introduction of this additional restriction on 'mono and di saccharides other than lactose' for Name of Product] for young children, coupled with the introduction of a maximum level for available carbohydrates are all significant changes). ISDI would also like to note the following comments: 1) The text, "…either added as ingredients, or constituents of ingredients and/or increased above the

	amount contributed by the ingredients by some other means," is a very wordy way of stating 'total amount present'. ISDI recommends that the sentence is simplified and this wording is deleted accordingly. 2) The following sentence, "National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ)," should be deleted. ISDI doesn't support a restriction on mono- and disaccharides other than lactose at 1.25g/100 kcal of available carbohydrate. This restriction is inspired by the WHO guideline to limit free sugars to less than 5% of total energy intake, which is a conditional recommendation. In addition, and as stated above, the recommendation is intended to apply to the total diet rather than individual products. 3) To achieve palatability, sucrose and/or fructose may be needed in certain formulas for example those based on plant protein, hydrolysed protein or lactose free. ISDI reiterates that all requirements incorporated into the revised codex standard must be enforceable, once the codex standard is transposed into regional /national law. ISDI considers, in that perspective, that the limits set for 'sugars (mono- and disaccharides other than lactose)' and 'available carbohydrates' are clear criteria. They are sufficient and appropriate for public health and are enforceable as they can be analytically measured.
d) Vitamins and Minerals	
Riboflavin **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 80 - 650 µg /100 kJ 19 - 155	
GUL	
~~155~~160	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The GUL per 100 kJ should be revised accordingly.
Vitamin B_{12} **Unit** **Minimum** **Maximum** **GUL** µg /100 kcal 0.1 - 2.0 µg /100 kJ 0.024 - 0.48	
Minimum	
0.~~1~~10	**Australia**
0.~~1~~10	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kcal should be revised accordingly.

Zinc **Unit** **Minimum** **Maximum** **GUL** mg /100 kcal 0.5 - 1.5 mg /100 kJ 0.12 - 0.36	
	Norway We are concerned of a GUL value of 1.5 mg zinc/100 kcal, since it can lead to overexposure of zinc. We propose a GUL of 1.0 mg. This value would avoid exceeding the UL of 7 mg/day for children 1-3 years old (IOM 2001, SCF/EFSA 2003), taking into account that children from 12 to 36 months also receive zinc from a progressively diversified diet.
Minimum	
0.~~5~~50	**Australia**
0.~~5~~50	**International Special Dietary Food Industries** ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The minimum per 100 kcal should be revised accordingly.
Vitamin A	
	Brazil In Brazil, vitamin A deficiency is found in some regions of the country. According to the Brazil National Demographic and Health Survey of Children and Women (PNDS – 2006[1]), vitamin A deficiency was found in 17.4% of children under 5 years of age and 12.3% of women of childbearing age. In children, the higher prevalence was found in the Northeast (19%) and Southeast (21.6%) regions of the country. In women, the higher prevalence was found in the Southeast (14%), Midwest (12.8%), Northeast (12.1%), North (11.2%) and South (8%) regions of the country. Moreover, Brazil implemented in 2005 a National Vitamin A Supplementation Program for children aged 6-59 months of age. Thus, Brazil is of the opinion that the addition of vitamin A should not be mandatory. It would be more appropriate for individual national authorities to require the mandatory addition of vitamin A at the national level. However, considering that the Committee agreed that there is sufficient evidence to require the mandatory addition of vitamin A to follow-up formula for young children, Brazil has not objections to the recommended minimum and maximum values.
	Norway

	We are of the opinion that a maximum of 180 ug RE is too high, and can lead to intakes of vitamin A exceeding the UL. EFSA has stated that children are particularly sensitive to excessive vitamin A intakes. Children from 12 to 36 months receive vitamin A from a progressively diversified diet, which will add to vitamin A received from [name of product] of young children. We propose a maximum of 120 ug RE vitamin A/100 kcal. This value is the average between the content of full fat milk (60 ug RE vitamin A/100 kcal) and the maximum of 180 ug RE vitamin A/100 kcal in the infant formula standard. Furthermore, a maximum of 120 ug RE vitamin A/100 kcal would be significant higher than the content in the breast milk of 85 ug RE vitamin A per 100 kcal.
[Vitamin D_3[9)]]	
[Vitamin D_3[9)]]	**Australia** Vitamin D insufficiency in young children is frequently documented, even in some lower latitude countries. For this reason Australia continues to support mandatory addition of vitamin D to [name of product] for young children at a minimum of 1.5µg/100kcal. As discussed at CCNFSDU39 the proposed minimum and maximum range accommodates the needs of populations in different countries and are in line with recommendations by the International Expert Group coordinated by the Early Nutrition Academy (Suthutvoravut et al 2015). In addition, intakes at the maximum level generally do not exceed the Upper Limit set by the IoM (IoM 2011). Recognising there are population differences internationally we support removal of the square brackets of the text in footnote 9. However, Australia does not support the limitation of Vitamin D to just Vitamin D3. We note that discussion at CCNFSDU39 suggested that the proposed limits should be as Vitamin D3 because footnote 10 provides a conversion for calciferol to International Units (IU) with no differentiation between D2 & D3. However, Australia considers the generic term for vitamin D – calciferol, as used in footnote 10 does allows for both forms (IoM, 2011). If the conversion was specific to vitamin D3, we believe the footnote would state 'cholecalciferol' for conversion to IU. Further to this, Australia notes the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG-010e_2015) lists both Vitamin D2 (ergocalciferol) and vitamin D3 (cholecalciferol) as permitted forms and that the use of the generic term calciferol in the footnote is consistent with that in the Standard for Infant Formula (Codex Stan 72-1981) and the proposed provisions for Follow-up for Older Infants. We therefore support removal of the square brackets and deletion of D3 as indicated
	Colombia Colombia supports a minimum value of 1.5 and a maximum value of 4.5, bearing in mind that the most common form is D3 with an absorption rate of 50%.
	Indonesia Indonesia proposes to open the square brackets

	Norway We propose a maximum vitamin D level of 3.0 µg/100 kcal, which would align the maximum level with the value agreed for follow-up formula for older infants. A caloric intake of 500 kcal with a minimum level of 3 µg/100 kcal would result in an intake of 15 µg vitamin D, accounting for 100% of DIRV of 15 µg (EFSA 2016), thus meeting vitamin D requirements alone. A value of 3 µg/100 kcal would not lead to excessive intakes.
	Philippines The Philippines supports deletion of the brackets on minimum (1.5µ/100kcal) and maximum values (4.5 µg) for Vitamin D. Vitamin D insufficiency in young children still exist even in some lower latitude countries. A maximum of 4.5µg/100kcal, which corresponds to 3 times the minimum level seems to be appropriate maximum level. We believe that a maximum limit for Vitamin D is needed due to its potential toxicity.
[Vitamin D_3[9)]] **Unit** **Minimum** **Maximum** **GUL** µg[10)] /100 kcal [1.5] [4.5] - µg[10)] /100 kJ [0.36] [1.08] -	
Minimum: 1.5 µg/100 kcal	
~~[1~~1.~~5]~~ 5	**Australia**
Maximum: 4.5 µg/100 kcal	
~~[4~~4.~~5]~~ 5	**Australia**
[4.5]	**International Special Dietary Food Industries** Noting that there is no request for comments at that stage on this topic which remains in square brackets and at step 3, ISDI is sharing its rationale ahead of CCNFSDU40 ISDI supports the mandatory addition of vitamin D to [name of product] for young children at a minimum level of 1.5 µg /100 kcal and a maximum level of 4.5 µg/100 kcal. Vitamin D deficiency is recognized as a public health concern for young children (Suthutvoravut et al, 2015). Inadequate vitamin D dietary intakes are observed in young children worldwide. Low vitamin D status is a global concern, even in regions with higher sunlight exposure. Daily consumption of 300-500ml of [name of product] for young children, with a vitamin D level up to 4,5 µg/100 kcal, as part of a diversified diet, will result in food intake which better covers the vitamin D needs of young children. And, importantly, this improved intake of vitamin D will be achieved without exceeding the recommended daily UL for vitamin D specified by EFSA of 50ug/day. Reference:

	Suthutvoravut U, Abiodun PO, Chomtho S, et al. 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, 2015; 67(2):119-32.
Minimum: 0.36 µg/100 kJ	
~~[~~0~~.36]~~ 36	**Australia**
Maximum: 1.08 µg/100 kJ	
~~[~~1~~.08]~~ 08	**Australia**
[1.~~08]~~ 1]	**International Special Dietary Food Industries** Noting that there is no request for comments at that stage on this topic which remains in square brackets and at step 3, ISDI is sharing its rationale ahead of CCNFSDU40 ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The maximum per 100 kJ should be revised accordingly.
[9) Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.]	
~~[~~[9)] Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.~~]~~	**Australia**
[9)] Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.]	**Canada** Canada supports the mandatory addition of vitamin D at a minimum level of 1.5 µg/ 100 kcal and a maximum of 4.5 µg/ 100 kcal. Vitamin D insufficiency is prevalent among young children globally. The IEG 2015 report (Suthutvoravut et al 2015) found that young children had inadequate vitamin D intakes in many parts of the world. Using serum 25-hydroxyvitamin D concentration to define vitamin D status, vitamin D deficiency (serum 25-hydroxyvitamin D <27.5 nmol/L or <50 nmol/L) was found in 10% of children aged 6-23 months in New Zealand, and in 34.9 and 42.8% of children aged 2-4.9 years in urban and rural areas of Indonesia, respectively. The same study also summarized surveys in young children from 4 countries in Southeast Asia which showed that vitamin D insufficiency may be a problem in many tropical countries, in addition to countries at higher latitudes such as those in North America and Europe. Similar reports have now emerged from sub-Saharan Africa with a study by Ludmir et al (2016) detecting low serum 25-hydroxyvitamin D (< 20 ng/mL, i.e., <50 nmol/L) in 19% of a sample of under-2 year olds in Botswana and another by Wakayo et al (2015) demonstrating similar low levels in 42% of school-aged children in central Ethiopia. A review by Palacios et al (2014) has summarized the global burden of vitamin D deficiency affecting infants and children (among others) across tropical and non-tropical countries.

	Minimum Level: Przyrembel and Agostoni (2013) noted that for a product such as FUF, the minimum vitamin D content should be between 1 and 1.3 µg/ 100 kcal, which are similar to the proposed minimum level. The recently revised EU regulations (2016) and the EFSA (European Food Safety Authority, 2014) recommend a minimum vitamin D amount of 2 µg/ 100 kcal in follow-on formula and infant formula, which is higher than the proposed minimum of 1.5 µg/ 100 kcal. Maximum Level: In Canada and the United States of America, the Dietary Reference Intakes (DRIs) for vitamin D were updated by the National Academy of Medicine (NAM) in 2011, and the Tolerable Upper Intake Level (UL) was set at 62.5 µg/day for children 1-3 years. Assuming a daily intake of 500 ml of this product and an energy density of about 60 kcal/100 ml, the proposed maximum of 4.5 µg/ 100 kcal would result in average intakes from these product/s at levels (calculated vitamin D intake from such products will be 13.5 µg/day) well below the UL. These data demonstrate that there is no risk of vitamin D toxicity associated with the proposed proposed level. The maximum level is also in line with the recommended maximum levels for vitamin D made in the report by the International Expert Group (IEG 2015). Refs: 1. Suthutvoravut U et al. 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. 2015; 67(2): 119-32. 2. Ludmir J et al. Vitamin D Status in Botswana Children Under 2 Years Old With and Without Active Tuberculosis. Am J Trop Med Hyg. 2016; 94(5):971-4. 3. Wakayo T et al. Vitamin D deficiency and its predictors in a country with thirteen months of sunshine: the case of school children in central Ethiopia. PLoS One. 2015; 10(3):e0120963. 4. Palacios C et al. Is vitamin D deficiency a major global public health problem? J Steroid Biochem Mol Biol. 2014; 144 Pt A:138-45 5. Przyrembel H and Agostoni C. Growing-up milk: a necessity or marketing? World Rev Nutr Diet. 2013;108: 49-55. 6. EFSA (2014). Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal, 2014; 12 (7): 3760, pp 106 7. IOM (2011). Dietary Reference Intakes for Calcium and Vitamin D.
Sodium chloride should not be added to [name of the product] for young children.	
	Australia Appendix II of the REP18/NFSDU includes the clause ‘No sodium chloride should be added to [name of product] for young children’. Australia has previously raised a consequential issue for further consideration (Australia’s response to the May 2017 Consultation paper on essential composition for young children) as this clause creates an inconsistency within the section B of Codex STAN 156-1987. The inclusion of this clause prohibits the use of sodium chloride and does not recognise the long-standing

	permission to use sodium chloride as a source of sodium in Follow-up formula as detailed in the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG-010e_2015). We understand sodium chloride is not widely used but may be added, for example if needed to balance mineral levels in milk-derived ingredients to compensate for natural variations in their mineral content. Australia understands the intent of this clause is to limit the amount of sodium. As an alternative to this clause Australia proposes adoption of a maximum limit, which is consistent with the approach used for follow-up formula for older infants. The maximum level of sodium in the current Codex STAN 156-1987 Follow Up Formula is 85 mg/100 kcal. The guiding principles for the revision of this standard for young children 12–36 months, includes accommodation of cows' milk, infant formula and breast milk. Whole cows' milk sodium levels range between 76 mg/100 kcal and 124 mg/100 kcal* (Atkinson et al 1995). Reduced fat and skim milk levels are higher again. Average levels in whole milk are approximately 95 mg/100 kcal (Sep 2016 eWG paper), however this does not account for variation. Australia therefore considers a maximum of 125 mg/100 kcal would be appropriate. *20-33 mmol/L, converted to 76–124 mg/100 kcal using an average energy of 62 kcal/100 mL References: Atkinson S, Alston-Mills B, Lonnerdal B, Neville M. Chapter 7 Minerals, Ions, and Trace Elements in milk B Major Minerals and Ionic Constituents of Human and Bovine Milks in Handbook of Milk Composition. Robert G Jensen (ed). Academic Press: 1995. Institute of Medicine 2011 Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride: a report of Standing Committee on the Scientific Evaluation on Dietary Reference Intakes and its Panel on Folate, Other B Vitamins, and Choline and Subcommittee on Upper Reference Levels of Nutrients. National Academy Press, Washington D.C. Koletzko B, Lien E, Agostoni C, Böhles H, Campoy C, Cetin I, Decsi T, Dudenhausen JW, Dupont C, Forsyth S, Hoesli I, Holzgreve W, Lapillonne A, Putet G, Secher NJ, Symonds M, Szajewska H, Willatts P, Uauy R; World Association of Perinatal Medicine Dietary Guidelines Working Group. 2008 The roles of long-chain polyunsaturated fatty acids in pregnancy, lactation and infancy: review of current knowledge and consensus recommendations. J Perinat Med. 2008;36(1):5-14. doi: 10.1515/JPM.2008.001. Nutrient Unit Conversion Factors, National Institutes of Health Dietary Supplement Label Database https://www.dsld.nlm.nih.gov/dsld/unitconversion.jsp, accessed 28 September 2018 Suthutvoravut U, Abiodun PO, Chomtho S, Chongviriyaphan N, Cruchet S, Davies PS, Fuchs GJ, Gopalan S, van Goudoever JB, Nel Ede L, Scheimann A, Spolidoro JV, Tontisirin K, Wang W, Winchagoon P, Koletzko B. (2015) Composition of follow-up formula for young children aged 12-36 months: recommendations of an international expert group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Annals of Nutrition and Metabolism 2015; 67(2):119 132. doi: 10.1159/000438495.

3.1.4 National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breast milk, and take into account the inherent levels of nutrients in cows' milk.	
3.1.4 National and/or regional authorities may add mandatory requirementsforessential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is ~~informed by~~ cognisant on the composition of breast milk, and take into account the inherent levels of nutrients in cows' milk.	**Philippines** We propose a slight modification of the last statement "If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow up formula for older infants (3.1.3 Section A). If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow up formula for older infantss (3.1.3 Section A) which is cognisant on the composition of breast milk, and take into account the inherent levels of nutrients in cow's milk. We are of the opinion that any additional optional nutrient can only have relevant beneficial effect if it is part of the composition of breast milk, which is the gold standard for complete foods for older infants and young children.
	Norway We strongly support this principle. We deem it imperative that national and/or regional authorities may amend nutrient levels if the nutritional needs of the local population and scientific justification warrants such deviation.
All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.	
	Philippines We support retention of the statement "All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation."
3.2 Optional Ingredients	
3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young childrenwhere the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.	
	Philippines The amount of optional ingredients should be adequate for the intended effect considering levels found in breastmilk since human milk is an ideal part of the progressively diversified diet up to two years of age and beyond. The levels of ingredients should mimic levels found in breastmilk in order to support the young children's physiological requirement for a particular optional ingredient. Ryan and Hay (2016) recommended that it is best to meet the children's nutritional needs during a critical time of growth and development of young children. Hence, the Philippines supports that the composition and levels of optional ingredients to be added in [name of product] for young children be based on the composition and levels of breast milk.

3.2.1 In addition to the ~~essential~~ compositional requirements listed under 3.1.3 Section B, other ~~ingredients, substances or nutrients~~ ingredients may be added to [name of the product] for young children~~where the~~ **in order to provide substances for particular nutritional purposes.** The safety and suitability of the optional ~~ingredient for particular nutritional purposes,~~ ingredients at the level of ~~use, is~~ use shall be evaluated ~~by national and/or regional authorities~~ and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also ~~permitted.~~ permitted **subject to 3.2.2 Section B[11].** **Footnote 11 The limits and footnotes applied to substances listed in 3.2.3 Section A are not necessarily appropriate for [name of product] for young children due to the different nutritional needs of young children versus older infants, and the difference in recommended daily intake for [name of product for young children versus Follow-up formula for older infants.**	**International Special Dietary Food Industries** ISDI recommends: • Alignment with the Codex Infant Formula Standard with regard to how the words 'ingredient' and 'substance' are used. • Deletion of the requirement for evaluation by a national or regional authority as this is more stringent than is applied to optional ingredients in the Infant Formula standard and to optional ingredients in Section A of this standard. • Correcting text in relation to Section A 3.2.3. This lists 'substances' that may added, not 'optional ingredients.' ISDI also notes that "essential" is not included in the Codex Infant Formula Standard, nor in section A 3.2.1 of this revised standard. ISDI is not opposed to its use, but would prefer for consistency in its use or not in the corresponding sections of the two parts of this revised standard. Amendment of last sentence proposed and footnote proposed to clarify permissions relating to optional ingredients listed in 3.2.1 Section A.
3.2.2 ~~When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.~~ **The [name of the product] for young children** shall contain sufficient amounts **of these substances** to achieve the intended effect.	**International Special Dietary Food Industries** ISDI recommends that the wording used is more aligned with that used in the infant formula standard. Again, this is to achieve consistency with regard to how the words, 'ingredient' and 'substance' are used. ISDI proposes same wording as proposed above for Section A 3.2.2 ISDI also recommends against referring to [name of product] for young children as 'formula' in this provision.
3.2.3 Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.	
3.2.3 ~~Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3~~	**International Special Dietary Food Industries** ISDI recommends changing the text as shown for greater clarity.

~~Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.~~ **Other** nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A). **The maximum or GUL levels stipulated for these nutrients may be revised to** take into account the inherent levels of nutrients in cows' **and goats'** milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.	