Request for Comments at Step 6 on the review of the Standard for Follow-up Formula (CXS 156-1987): proposed draft essential composition requirements

Comments suggested by ISDI

General Comment

ISDI recommends consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ. The 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.

Section A = OI

Text proposal	**Comment category**	**Rationale for change**	**ISDI text proposal**
3.1.3 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 should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.	Substantive	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.	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.**

		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.	

		○ 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.	
3.1.3 footnote 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).	Editorial	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.'	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 shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).
3.1.3 Linoleic acid **GUL** 335 mg/100 kJ	Technical	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.	GUL: 330 mg/100 kJ
3.1.3 footnote 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.	Editorial	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.	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.
3.1.3 Vitamin E **Minimum** 0.5 mg/100 kcal **GUL** 5 mg/100 kcal	Technical	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.	Minimum: 0.50 mg/10 0kcal GUL: 5.0 mg/100 kcal
3.1.3 Vitamin K **Minimum** 4 ug/100 kcal	Technical	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.	Minimum: 4.0 ug/100 kcal
3.1.3 Riboflavin **GUL** 119 ug/100 kJ	Technical	ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184 between kcal and kJ.	GUL: 120 ug/100 kJ

		The GUL per 100 kJ should be revised accordingly.	
3.1.3 Vitamin B_6 **GUL** 175 ug/ 100 kcal 41.8 ug /100 kJ	Technical	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: 180 ug/100 kcal and 43ug/100 kJ
3.1.3 Vitamin B_{12} **Minimum** 0.1ug/100 kcal	Technical	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.	Minimum: 0.10 ug/100 kcal
3.1.3 Pantothenic acid **GUL** 478 ug/100kJ	Technical	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.	GUL: 480ug/100 kJ
3.1.3 Biotin **Minimum** 0.4 ug/100kJ	Technical	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.	Minimum: 0.36ug/100 kcal
3.1.3 Footnote 17 **Maximum** 0.6 mg/100kJ	Technical	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.	Maximum: 0.60mg/100 kJ
3.1.3 Phosphorus **Minimum** 6 mg/100kJ	Technical	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.	Minimum: 6.0mg/100 kJ
3.1.3 Magnesium **Minimum** 5 mg/100kcal	Technical	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.	Minimum: 5.0 mg/100 kcal
3.1.3 sodium **Minimum** 5 mg/100kJ	Technical	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.	Minimum: 4.8 mg/100kJ
3.1.3 Iodine **GUL**	Technical	ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184	GUL: 14 ug/10 0kJ

14.3 mg/100kJ		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.	
3.1.3 Selenium **Minimum** 2 ug/100kcal **GUL** 9ug/100kcal	Technical	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.	Minimum: 2.0 ug/100 kcal GUL: 9.0 ug/100 kcal
3.1.3 Zinc **Minimum** 0.5 mg/100kcal	Technical	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.	Minimum: 0.50 mg/100 kcal
3.2.3 Taurine **Maximum** 3 mg/100kJ	Technical	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.	Maximum: 2.9 mg/100 kJ
3.2.3 DHA **GUL** 30mg/100kcal (7.2mg/100kJ)	Substantive	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: 50 mg/100 kcal (12mg/100 kJ).
Explanation of GULs	Editorial	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.	

Section B = YC

Text proposal	**Comment category**	**Rationale for change**	**ISDI text proposal**
3.1.3 c) footnote 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.]	Technical, editorial and substantive	This footnote is still in square brackets and ISDI will provide further comments for CCNFSDU40. ISDI supports the exclusion of all references to 'sweet taste' from footnote 4 because it is complex, subjective and it is not enforceable. ISDI strongly supports the efforts by CCNFSDU to limit sweetness and to restrict the level of mono- and disaccharides from all sources other than lactose at 2.5 g/100 kcal of available carbohydrate. At this maximum level, 'mono and di saccharides other than lactose' would contribute 10% of the products total energy. This aligns with the WHO guideline (March 2015) 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 (as these restrictions are NOT included in the current codex standard). 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 contrary to the strong recommendation to limit free sugars to less	**Text at STEP 3** [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 **in products such as [Name of Product] based on plant protein, hydrolysed protein or lactose free].** ~~Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]~~ **Clean copy:** [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Mono- and disaccharides, other than lactose should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source **in products such as [Name of Product] based on plant protein, hydrolysed protein or lactose free].**

		than 10% of total energy intake. 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. In this regard, ISDI considers whether it would be more meaningful to include palatability in the footnote. 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 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.	
3.1.3 d) Riboflavin **GUL** 155 ug/100 kcal	Technical	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 should be revised accordingly.	GUL: 160 ug/100 kJ
3.1.3 d) vitamin B_{12} **Minimum** 0.1 ug/100kcal	Technical	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.	Minimum: 0.10 ug/100 kcal.
3.1.3 d) zinc **Minimum** 0.5mg/100 kcal	Technical	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.	Minimum: 0.50 mg/100 kcal.
3.1.3 d) vitamin D_3 **Maximum** [4.5] ug/100kcal	Technical	This text is still in square brackets and ISDI will provide further comments for CCNFSDU40. ISDI supports the maximum limit at 4.5 ug/100kcal. There is no safety issue with the maximum level.	**Text at STEP 3** Maximum: 4.5 ug/100kcal.
3.1.3 d) vitamin D_3 **Maximum** [1.08] ug/100kJ	Technical	This text is still in square brackets and ISDI will provide further comments for CCNFSDU40. ISDI suggests consistent use of 2 significant figures for nutrient limits applying conversion factor of 4.184	**Text at STEP 3** Maximum: 1.1ug/100 kJ.

		between kcal and kJ. The maximum per 100 kJ should be revised accordingly.	
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 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.	Editorial and substantive	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.	**3.2.1** 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 children ~~where~~ **in order to provide substances for particular nutritional purposes**. The safety and suitability of the optional ingredient**s** ~~for particular nutritional purposes~~, at the level of use, ~~is~~ **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 **subject to 3.2.2 Section B[1].**
3.2.2 When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.	Editorial	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.	**3.2.2** ~~When any of these ingredients, substances or nutrients is added the formula~~ **The [name of the product] for young children** shall contain sufficient amounts **of these substances** 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	Editorial	ISDI recommends changing the text as shown for greater clarity.	**3.2.3.** ~~Additional~~ **Other** nutrients may also be added to [name of the product] for young children provided

[1] 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.

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.			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** ~~and~~ 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.