REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156-1987)

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

Second Consultation Paper
Submitters Response Form

June 2016

Please respond by **19th July 2016**

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

Name of Member Country/Organisation: **Helen Keller International (HKI)**

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

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

Protein

Protein

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

Protein

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	[1.8] or [1.65]	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39]	[0.84] or [0.72] or [0.60]	-

Minimum

☒ Codex Infant Formula standard 1.8 g /100 kcal 0.43 g /100 kJ	☐ 1.65 g /100 kcal 0.39 g /100 kJ

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

NOTE: The discussion of protein intakes needs to be based on realistic amounts of follow-up formula consumed each day. In Table 2 of the 2nd consultation paper, the following is used to support a maximum of 2.5 g/100 kcal "The protein requirement for older infants is calculated to 10.2 g per day, based on the WHO/FAO/UNU protein requirements (2007) and the WHO Multicenter Growth Study Growth Standards (2006). With a representative caloric intake of 500kcal/day a maximum limit of 2.5 g/100 kcal corresponds to 12.5 g protein per day, which exceeds the requirement of 10.2 g per day."

The use of 500kcal/day of follow-up formula is excessive as discussed in the Vitamin C section below. On page 44 it states "From one year of age many national guidelines recommend the introduction of between one and two serves per day (up to 500ml) of cows' milk (2013 eWG)." The number of kcal in 500ml cow's milk is about 300kcal. But later when making calculations of the amount of nutrients per 100kcal to reach the desired RNIs, a higher energy content of 500kcal is used which is nearly 800ml, not 500ml the maximum mentioned above. This larger suggested amount of follow-up formula for both older infants and young children is too high, allowing little room for breastmilk or complementary foods before the child's energy needs are met. The error was made because the original citation was 500kcal of milk for infants <6 months (p. 7, 1st Consultation Paper).

The discussion on protein should therefore use 300kcal rather than 500kcal of follow-up formula, and in this case, even a level of 3.5 g/100 kcal would not exceed 10.2 g per day.

We urge the committee to address this error.

Maximum		
☐ 3.5 g /100 kcal 0.84 g /100 kJ	☐ Codex IF std 3.0 g /100 kcal 0.72 g /100 kJ	☐ EFSA 2.5 g /100 kcal 0.60 g /100 kJ
Please provide scientific justification and applicable references for your response:		
Footnote 6 The majority of the eWG supported retaining elements of footnote 6. [6)Follow-up formula based on ~~non-hydrolysed~~ **intact** milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated		
Regarding formulas based on **hydrolysed** protein, please state whether you think that all, or only those containing less than [2.25 g/100 kcal] should be clinically evaluated.		
☐ All formulas based on hydrolysed protein should be clinically evaluated	☐ Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated	
Please provide justification for your response.		
Regarding formulas based on **intact/non-hydrolysed** protein please note that your responses to these questions do not imply that you support a minimum of 1.8 g/100 kcal or 1.65 g/100 kcal. They will be used to refine the wording in square brackets if the eWG cannot come to agreement on a minimum value. Please state whether you support the proposal to amend the reference these types of formulas to **intact milk protein**.		
☐ intact milk protein	☐ non-hydrolysed milk protein	
Please provide justification for your response.		
Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required for any formulas based on intact/non-hydrolysed milk protein?		
☐ Yes, all formulas containing 1.65-1.8 g/100 kcal require clinically evaluation	☐ Yes, all formulas containing 1.65-2.0 g/100 kcal require clinically evaluation	☐ no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal
Please provide justification for your response.		
If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for formula based on intact/non-hydrolysed milk protein, do you support the recommendation that the minimum protein level which requires clinical evaluation is placed in the footnote, rather than in the table? See **Error! Reference source not found.** above		
☐ Yes	☐ No	

Vitamin K

Vitamin K			
The Chairs propose that the following drafting of vitamin K requirements for follow-up formula for older infants is recommended for adoption by the Committee: **Vitamin K**			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	4	-	27
mg/100 kJ	1	-	6.5
Please comment on this proposal and provide your justification:			

Vitamin C

Vitamin C

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

Vitamin C[15)]

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

[15)] expressed as ascorbic acid

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

Minimum levels

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

Please provide your preferred response: We believe there is an error in the 2nd Consultation paper which affects the amount proposed for vitamin C. On page 44 it states "From one year of age many national guidelines recommend the introduction of between one and two serves per day (up to 500ml) of cows' milk (2013 eWG)." The number of kcal in 500ml cow's milk is about 300kcal. But later when making calculations of the amount of nutrients per 100kcal to reach the desired RNIs, a higher energy content of 500kcal is used (p. 8, 17, 21, 69) which is nearly 800ml, not 500ml the maximum mentioned above. This larger suggested amount of follow-up formula for both older infants and young children is too high, allowing little room for breastmilk or complementary foods before the child's energy needs are met. The error was made because the original citation was 500kcal of milk for infants <6 months (p.7, 1st Consultation Paper). "Lowering the minimum requirement to 1µg/100 kcal would still enable **young infants (0-6 months) to meet the WHO/FAO requirements assuming average intake of 500kcal of formula**."

Table 1 illustrates why 500kcal is not appropriate for older infants and young children. For breastfed children, the proposed 500kcal/day in addition to average breast milk intakes is completely untenable. The infant would exceed his/her daily caloric requirement from this much follow-up formula with no complementary foods eaten at all. The toddler would essentially have no room for any complementary foods. Clearly, this amount of follow-up formula would have to replace breast milk intake just to get down to caloric requirements and it would have to be much lower to make room for other complementary foods.

For non-breastfed children, for infants (< 12 months of age), 500kcal/day from follow-up formula is extremely high and leaves virtually no room for complementary foods. After 12 months, the proposed intake of follow-up formula is considerably higher than the milk intake of a breastfed child. This intake level is at the upper end of the range of milk intakes recommended for non-breastfed children receiving no other animal-source foods. It seems hard to justify that the majority of calories should come from follow-up formula even in a non-breastfed child.

Table 1. Comparison of energy requirements, breastmilk intakes and proposed energy from FUF*

Age of infant	Bmilk intake	Proposed amt of FUF	Total expected intake for bfed child	Energy required	% from Bmilk	% from FUF	% from Bmilk or FUF
	(kcal/d range)	(kcal/d)	(kcal/d)	(kcal/d)			
6-8 mos	413-486	500	913-986	600	69-81%	83%	152-164%
9-11 mos	375-379	500	875-879	700	54%	63%	125-126%
12-23 mos	313-346	500	813-846	900	34-38%	56%	90-94%

* PAHO and WHO. Guiding principles for complementary feeding of the breastfed child. 2003. http://www.who.int/maternal_child_adolescent/documents/a85622/en/

Additionally, Watson and Heath (2013, The role and use of fortified milk-based products in the diets of older infants and young children, MPI Technical Paper No: 2013/40, New Zealand), report "Children greater than six months and up to 12 months of age in Germany (10,15), Ireland (16), UK (9), and Norway (17) had a mean intake of 314 g/day (305 mL/day) or in the USA (8) 628 mL/day, while children older than 12 months had a mean fortified milk-based product intake of 353 g/day (343 mL/day) in Germany (10,15), Ireland (16), UK (9), and Norway (18)." Thus 500 kcal/day or 800/ml is higher than reported in the literature as well for intake of follow-up formula.

On p. 7, "Based on an estimated intake of formula of 500kcal per day this would provide the adequate intake level established by the IOM (50mg vitamin C per day)." This should be changed to "Based on an estimated intake of formula of **300kcal** per day this would **provide 60%** of the adequate intake level established by the IOM (30mg/50mg) vitamin C per day.

It becomes especially important if a lower level of vitamin C (4mg/100kcal) is chosen which would provide 12mg/50mg or 24% of adequate intake.

We therefore support the 10 mg/100 kcal of vitamin C.

Zinc

Zinc

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

Zinc

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

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

Please comment on this proposal and provide your justification:
We agree.

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)

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

Docosahexaenoic acid[21)]

Unit	**Minimum**	**Maximum**	**GUL**
% fatty acids	[-] or [0.3]	-	0.5

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, **[a minimum of [x% fatty acids] should be added** arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

If added, minimum level

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

Please provide scientific justification for your response:
IF DHA is added, it should be in quantities that are likely to have impacts, and not be so minimal that is only serves as a marketing tool, not a nutritional enhancement.

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

It should be placed within the table.

Optional Ingredients: L(+) lactic acid producing cultures

Optional addition L(+) lactic acid producing cultures		
[3.3.2.4 Only L(+) lactic acid producing cultures may be used]		
Several eWG members noted there are two purposes for the addition of L(+) lactic acid producing cultures referring to both the acidification of formula and supplementation with probiotics. Please indicate if you consider that the sub-Section 3.3.2.4 (Optional ingredients) should refer to one, or both types of addition.		
☐ Two purposes: acidification of formula **and** supplementation with probiotics	☐ For the purpose of acidification of formula **only**. Contains minimal amounts of viable bacteria.	☐ For the purpose of supplementing with probiotics **only**
Please provide justification for your preferred response:		
If you consider that standard should allow for both types of addition, please indicate if you think that this should be captured within 3.3.2.4, or as two separate clauses within the Optional Ingredients Section (Section 3.3.2).		
Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.		
☐ The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence ☐ Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria ☐ For the purpose of producing acidified formulas ☐ Non-pathogenic lactic acid cultures may be used **OR** ☐ No additional wording is required. Alignment with the Codex Infant Formula Standard		
Please provide justification for your response and any proposed draft text:		

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

Proposed approach

Mandatory (core) composition
Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is : • Evidence to support nutritional issues for young children of global concern; • Contribution to the overall nutritional quality/integrity of the product; • The contribution of key nutrients from cows milk for equivalence; and • The strength of committee support for including in the core composition.
Answer: Yes, we support the mandatory core
Should there be a minimum number of principles that each nutrient must meet in order for it to be considered part of the mandatory (core) composition, or requiring specific compositional parameters in follow-up formula for young children? Please state what this should be.
*Answer:*Yes

An additional principle should be the delineation of the amount of product that children ages 12-36 mo should consume. This has not been stated in this current proposed Standard but is clearly stated in the Infant Formula Standard CODEX STAN 72 – 1981 :

a) The mean intake of prepared formula for infants from birth to six months of age is 750 ml per day, and
b) a representative body weight for an infant over this period is 5 kg, and
c) a representative caloric intake of an infant over this period is 500 kcal per day (or 100 kcal/kg/day).

In order to compare the amount of nutrients proposed per 100 kcal, there should be a statement such as this that illustrates expected intake of the product. In the consultation paper, it states "On page 44 it states "From one year of age many national guidelines recommend the introduction of between one and two serves per day (up to 500 mL) of cows' milk (2013 eWG)." The number of kcal in 500 ml cow's milk is about 300 kcal and the amount in one serve would be 150 kcal. The use of 500 kcal in portions of the consultation paper is excessive since the child this age should be getting more than half of its caloric intake from complementary foods, not liquid milk products.

Agreement on the expected amount will then allow a determination of how much of a particular nutrient is expected to be consumed by the young child from this product. This would then allow a determination of the percent of the Reference nutrient intake or INL98 from FAO/WHO Vitamins and Mineral requirements in Human Nutrition.2nd Edition. FAO/WHO, 2004 (for all nutrients except copper, manganese and phosphorus) as was done for the GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN CAC/GL 8-1991. A table should be given showing for each nutrient the reference intake being used to calculate the nutrient amounts if they differ from FAO/WHO 2004 (for example for protein requirements which are from WHO/FAO/UNU protein requirements (2007)). This will allow one to understand differences in approaches and results for the different Standards.

There should be consistency between principles and requirements in the Standards for products for this age group, including the amount of energy from the product to be consumed on a daily basis.

Voluntary Nutrient Additions

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

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

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

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

Answer:
Please provide justification for your answer:

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

Answer:
Please provide justification for your answer:

Optional Ingredients

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

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

Answer:
Please provide justification for your answer:

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

Answer:
Yes they should 'take into account levels in human milk' for follow-up formula for young children.

Please provide justification for your answer:
These serve as breast-milk substitutes and therefore their nutrient contents should 'take into account levels in human milk' for follow-up formula for young children.

QUESTION:
Do you support deletion of the third bullet point for follow-up formula for young children?

Answer:
Please provide justification for your answer:

Energy contribution from macronutrients

Energy contribution from macronutrients

Please provide comment and justification as to whether it is necessary to define specific macronutrient percentage contribution to overall energy.

Answer: By setting minimums and maximums for protein and fat, this means that carbohydrate levels could be excessive allowing for high sugar content in the product. Thus there should be a maximum set for free sugars.

Energy

Energy

Members of the eWG have recommended that the energy density of follow-up formula for young children should be established, and the following levels proposed:

Energy

Unit	Minimum	Maximum

kcal/100 ml	[60]	[45]	[70]
kJ/100 ml	[250]	[188]	[293]

Should the range for the energy density of follow-up formula for young children accommodate the energy content of full fat cows' milk *and* reduced fat cows' milk, or align with the minimum energy density of follow-up formula for older infants?	
☒ FUF-older infants & full fat cows' milk 60 kcal/100ml 250 kJ/100 ml	☐ Reduced fat cows' milk (~1.5-2% fat) 45 kcal/100 ml 188 kJ/100 ml
Please provide justification for your answer The fat content of breastmilk is 70 kcal/100 ml as reported in Table 24 of the consultation paper. Fat is often limited in complementary foods of young children in developing countries, so the minimum should not be lower than that found in full fat cow's milk. While children over 24 mo of age might be able to use a lower fat milk, this standard should focus on the requirements of the age 12-24 mo group that has the highest need for fat.	
Do you support establishing a maximum energy density for follow-up formula for young children? If so, do you have suggestions as to how this level should be derived?	
Answer:	

Protein

Protein	**Protein**
Considering the eWG's varied views, are minimum and maximum requirements necessary? If so, please state your preferred approach on how to establish protein requirements?	Considering the eWG's varied views, please your preferred approach on how to establish protein requirements? Please comment also if there should be a recommended appropriate contribution of protein to energy of follow-up formula for young children.
Please provide justification for your answer	
Should there be requirements for protein quality? If so how this might be achieved? Please consider both the current Follow-up formula standard, and proposals within the draft standard for older infants.	*Please provide justification for your answer*
Please provide justification for your answer	

Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
☐ Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	☒ Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
☐ Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	☐ Alternative value, please specify
Please provide justification for your answer Fat is an essential nutrient for this age group and often limited in diets of young children in low income countries.	
Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?	
☒ Proposed FUF-older infants & cows' milk 6.0 g/100 kcal 1.4 g/100 kJ	☐ Alternative value, please specify

Please provide justification for your answer There should be a limit on total energy in order to limit the addition of carbohydrates and the sugar content of the product.

Lipids

Lipids	
Based on the eWG recommendation to give consideration to the fatty acid profile of follow-up formula for young children, including maximum levels for trans fat, and noting the levels in full fat and reduced fat cows' milk, please state your preferred levels (with justification) as below: Should levels for linoleic acid, α-linolenic acid and phospholipids be established for follow-up formula for young children? Please stipulate what these levels should be; min, max, GUL.	
Please provide justification for your answers. ALA is often low in diets and young children need this for development.	
Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?	
☒ Yes Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG? ☒ Yes ☐ No ☐ Alternative, please specify and provide justification for your answer.	☐ No
Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?	
☒ Should this level be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk? ☐ ☐ No ☐ Alternative, please specify and provide justification for your answer.	☐
Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
☐ Yes Please state what the maximum level should be, and provide justification for your answer.	☐ No
Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (*Commercially hydrogenated oils and fats shall not be used in follow-up formula*) also apply to follow-up formula for young children?	

Please provide justification for your answer.

Carbohydrates

Total Available Carbohydrates	
Is a minimum available carbohydrate level required, if a consensus is reached on establishing minimum and maximum levels for energy, protein and total fat?	
☐ Yes	☐ No
Please provide your rationale:	
If you support establishing a minimum available carbohydrates level, what level do you support?	
☒ Full fat cows' milk 7.5 mg/100 kcal 1.8 mg/100 kJ	☐ IEG 2015 and proposed Codex FUF-OI 9.0 mg/100 kcal 2.2 mg/100 kJ
Please provide your rationale: The reduction in free sugars is a goal for young child feeding and setting a minimum that is equal to the amount in cow's milk means that children do not need to be offered products higher in sugar.	
If limits are established for sugars, is there a need to also set a maximum/GUL for total available carbohydrates?	
☒ Yes	☐ No
Please provide your rationale: Without setting a maximum, but having maximums for protein and energy, means higher carbohydrate and thus higher sugar products can be produced. We want to limit sugar consumption not allow it to be high in young children. .	
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?	
☒ Yes, a maximum level should be established	☐ Yes, a GUL level should be established
Please provide your rationale: Without setting a maximum, higher sugar containing milks can be produced, with children becoming accustomed to sweetened products early on, affecting their later taste preferences.	
If you support establishing a maximum/GUL, do you support 14 mg/100 kcal (3.3 mg/100 kJ)?	
☐ Yes	☐ No (please specify your alternative).
Please provide your rationale:	

Carbohydrates footnote		
Free sugars While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.		
☐ Proposed Codex FUF-OI Standard Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does	☒ IEG 2015 Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	☐ An alternative level (please specify)

not exceed 20% of available carbohydrate.		

Please provide your rationale:

The phrase, unless needed as a carbohydrate source, is vague and allows sugars to be added in place of protein and fat which has maximum levels. Who determines "unless needed", and based on what (costs, taste preferences"? This is too ambiguous. Global nutrition guidance should be followed in order to limit free sugars.

Lactose

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

Please provide your rationale:

Other permitted carbohydrates

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

Please provide your rationale:

Iron

Iron

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

Iron

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

Should a maximum level or GUL be established for iron?

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

Please provide your rationale:

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

☐ Maximum (Proposed Codex FUF-OI) 2.0 mg/100 kcal 0.5 mg/100 kJ	☐ GUL (IEG 2015) 3.0 mg/100 kcal 0.7 mg/100 kJ

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

Calcium

Calcium			
No consensus was reached on the requirements for calcium in follow-up formula for young children. Noting that full fat cows' milk contributes 190 mg calcium/100 kcal (range 184 - 201 mg/100 kcal) and the average amount of calcium in reduced fat cows' milk is 259 mg/100 kcal (range 240 – 280 mg/100 kcal), Please provide comment on the below options:			
Calcium Unit mg/100 kcal mg/100 kJ	**Minimum** [50] [90] [200] [18] [22] [24] [48]	**Maximum** [N.S.]	**GUL** [180] [NS] [43]
Minimum:			
☐ Current Codex FUF standard 90 mg/100 kcal 22 mg/100 kJ		☐ Proposed Codex FUF standard for older infants 50 mg/100 kcal 12 mg/100 kJ	
☒ IEG 2015 200 mg/100 kcal		☐ Alternative value, please specify	
Please provide justification for your answers. We believe there is an error in the 2nd Consultation paper which affects the amount proposed for Calcium. On page 44 it states "From one year of age many national guidelines recommend the introduction of between one and two serves per day (up to 500 mL) of cows' milk (2013 eWG)." The number of kcal in 500 ml cow's milk is about 300 kcal. But later when making calculations of the amount of nutrients per 100 kcal to reach the desired RNIs, a higher energy content of 500 kcal is used (p. 58 in the Calcium table states 500 kcal of formula) which is nearly 800 ml, not 500 ml the maximum mentioned above. This larger suggested amount of follow-up formula for both older infants and young children is too high, allowing little room for breastmilk or complementary foods before the child's energy needs are met. The error was made because the original citation was 500 kcal of milk for infants <6 mo (p. 7, 1st Consultation Paper). A complete explanation of the reason 500 kcal is too high is given under the vitamin C question above. For calcium, if 500 ml is used (rather than 500 kcal), then the child would receive on average with 2 cups of follow-up formula, 600 mg if the IEG recommendation of 200 mg/100 kcal is used. We agree with the IEG explanation: "The 2015 IEG deemed milk and dairy products good sources of bioavailable calcium in young children69. It proposed a minimum level of 200 mg/100 kcal for follow-up formula for young children, based on an average consumption of 300 ml/day and the energy density of whole cows' milk. The IEG 2015 stated that this would be equivalent to about 40% of the recommended intake established by the WHO/FAO (500 mg/day) 69."			

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

Calcium	
Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included? Ratio calcium/phosphorus	
Min 1:1 / **Max** 2:1	
☐ Yes	☐ No
Please provide your rationale:	

Vitamin A

Vitamin A			
No consensus was reached on the establishment of a minimum or maximum vitamin A value. Please provide scientific rationale to support your preferred value: Vitamin A [x)]			
Unit	Minimum	Maximum	GUL
µg RE/100 kcal	[75] [60] [50]	[225] [180]	[200] [180]
µg RE/100 kJ	[18] [14] [12]	[54] [43]	[48] [43]
[x)] expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.			
Minimum			
☐ Current Codex FUF Std & proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	☐ IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	☐ WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ	
Please provide your rationale:			
Maximum			
☐ Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	☐ Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ		
Please provide your rationale:			
GUL			
☐ WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ	☐ IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ		
Please provide your rationale:			
Do you support the footnote below, agreed to by the Committee for follow-up formula for older infants (REP16/NFSDUE Appendix III)?			

[x] expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.
☐ Yes ☐ No

Vitamin D

Vitamin D	
Do you support that mandatory addition of vitamin D to follow-up formula for young children?	
☐ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer:	
Please state whether vitamin D should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer:	

Zinc

Zinc	
Do you support that mandatory addition of zinc to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: *This should match the FUF for older infants*	
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: *This should match the FUF for older infants*	

Vitamin C

Vitamin C	
Do you support that mandatory addition of vitamin C to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: *This should match the FUF for older infants*	
Please state whether vitamin C should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: *This should match the FUF for older infants*	

Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: *This should match the FUF for older infants*	
Please state whether vitamin B12 should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: *This should match the FUF for older infants*	

Riboflavin

Riboflavin	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: This should match the FUF for older infants	
Please state whether riboflavin should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: This should match the FUF for older infants	

Sodium

Sodium	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
☒ Yes	☐ No
Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.	
Answer:Need to compare amounts in breastmilk and cow's milk. If only full fat cow's milk is allowed, then sodium levels can be lower.	
Please state whether sodium should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: Need to compare amounts in breastmilk and cow's milk.	

SCOPE & LABELLING

Scope & Labelling When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.
Do you consider that any of the current labelling provisions for follow-up formula can be adopted as

is? If so, which provisions? YES

Please provide justification for your answer.
9.1.3; 9.1.4; 9.2; 9.3; 9.4; and 10 can be adopted as is as they do not refer to the name of the products which we believe needs to be intensively discussed. Throughout the text of the standard the word 'food' must be changed to 'product' in line and consistent with the decision made at the last meeting that follow-up formula will be referred to as a product not food in the definitions section 2.1.1.

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

Labelling provisions in 9.1, 9.5, 9.6, need to be revised.

Firstly, section **9.1 and 9. 1.1** must be revised throughout to replace the word 'food' with the word 'product' to be in line and consistent with the decision made at the last meeting that follow-up formula will be referred to as a product not food in the definitions section 2.1.1. Thus as examples, the title of 9.1 must read 'The Name of the Product' and 9.1.1 must read 'The name of the product shall be…'

Secondly, we believe that the evidence points to the need for consumer protection reasons to give different names to the 2 products now included in this standard – the one for older infants and the one for young children. The justification for this recommendation is that the word 'formula' implies a product that meets the normal nutritional requirements of whoever is consuming the product. The definition of infant formula in the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72 – 1981) defines in 2.1 infant formula as meaning "a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding". Thus the term 'formula' has become synonymous with a product that meets normal nutritional requirements.

We thus strongly suggest the product for young children should have a different name that does not include the word formula, since it does not provide by itself the normal nutritional requirements of the target group aged 12-36 months. The use of the word 'formula' would be misleading, and the product could potentially be fed incorrectly as a complete replacement for all foods.

The Merriam Webster dictionary defines formula as "a (1): recipe (2): prescription b: a milk mixture or substitute for feeding an infant." Based on both common usage of the word and the Codex definition of infant formula, a formula has become considered as meeting the normal nutritional requirements of the young infant (<6 mo of age).

Functionally, any milk product for 6-36 months of age will be used alongside other foods, displacing consumption of breast milk. Milks targeted at this vulnerable age group must be differentiated from infant formula to avoid misleading consumers and more importantly potentially causing negative health outcomes such as malnutrition.

We also note that translations of the terms used for 'infant formula' show that in the many commonly used languages (French, Spanish, Portuguese, Chinese, Arabic, Hindi, Bengali) the term for 'infant formula' either includes infant, formula or like mother's milk: Leche Maternizada, formula infantile - (Spanish); Lait Maternisé (French); Fórmula Infantil (Portuguese)l Yīng yòu'ér (Infant) nǎifěn (dried milk) 婴幼奶粉 (Mandarin Chinese); aarambhik phaarmoola (baby formula) (Hindi); halib 'atfal □□□□ □□□□□ (baby milk) (Arabic); □□□□ □□□□□ Śiśu Sutra (infant formula) (Bengali). Thus 'baby' (the age range of 0-12 months) is commonly used with the word 'formula', but 'child' (potentially older than 12 months) is not combined with the word 'formula'.

In contrast to the previous follow-up formula Standard, which was nutritionally suitable for older infants, the nutrient content of the now two proposed follow-up formula products differ substantially and thus should have distinctly different names and clear definitions in order to ensure that they are clearly distinguished from each other and thus avoid any potential consumer misinformation. This need for differentiation is further substantiated by research from the Helen Keller International Assessment and Research in Child Feeding (ARCH) Project, published in the Maternal and Child Nutrition Journal, that clearly showed that the manufacturers of these two products and of infant formulas market the range of products with the same/similar names, labels, designs, colors, and messages (paper available through open access at http://onlinelibrary.wiley.com/doi/10.1111/mcn.12269/epdf and attached to this submission). Based on

the proposed significantly different composition, it becomes necessary for the consumer to easily be able to differentiate between the 2 products under discussion.

We thus also believe that the name of the Standard 'Standard for Follow-up Formula (CODEX STAN 156-1987)' also needs to be opened for review.

Using the term 'Follow-up Formula' in the name of the standard, in the scope and in the 2 product names implies that both products could both be used for infants. Research has shown that mothers have interpreted 'Follow-up Formula' in this manner in the United Kingdom, where 16% of mothers in a 2010 national infant feeding survey reported that they first used follow-up formula before 6 months of age. Of mothers who had never worked, 26% reported that they had given their baby follow-on formula before 6 months of age (Infant Feeding Survey 2010). One-third (32%) of mothers reported they did not know the difference between various breast-milk substitute products, and health workers were unable to differentiate them as well (Crawley and Westfield, 2016, Infant Milks in the UK: A Practical Guide for Health Professionals – February 2016). In Senegal, nearly 10% of mothers of infants and children under age two were unable to state what stage of formula they gave their infants (ARCH research, 2016, unpublished analyses). Other research by Cattaneo et al. has also shown the confusion that exists between these different products amongst mothers, especially considering the way manufacturers label these products, clearly indicating the need for Codex to address this critical issue for the reason of consumer protection. Cattaneo et al. found that only 43% of mothers in a study in Italy were able to assign the correct meaning, in terms of age of use, after careful reading of a follow-up formula advertisement (Cattaneo et al. Archives of Disease in Childhood 0, 1–6. 2014)

As reported by Watson and Heath (2013, The role and use of fortified milk-based products in the diets of older infants and young children, MPI Technical Paper No: 2013/40, New Zealand), "recommendations for the minimum age of follow-up formula introduction are not always followed. France, Ireland, Luxembourg, and the United Kingdom all reported introduction earlier than their country's recommendation, as did the developing countries Ghana and the Philippines. There is a large range in the age at which follow-up formula was first introduced to the child. The earliest follow-up formula introduction reported was at one month by 2% of children in a United Kingdom study of 9,416 mothers (8). Even within countries there was a range of ages at which follow-up formula was introduced, such as in Sweden, where 44% of children were introduced to follow-up formula at less than four months old (11), 30.5% at four to six months, and 50% at six months or older… Rates of follow-up formula consumption at or before six months of age were reported by eight developed countries and three developing countries."

Follow-up formula for young children (12-36 months) designed by this standard could therefore potentially be fed to older infants (6 to 12 months) with no negative nutritional consequences if consumed in adequate amounts, hygienically prepared, and with the child receiving complementary foods. However if follow-up formula for young children is the only product fed to an infant < 6 months of age, nutritional deficiencies would most definitely result since the proposed composition of follow-up formula for young children only requires 13 nutrients, while the Infant Formula Standard and the proposed follow-up formula for older infants both require 32 nutrients. For example, thiamin deficiency due to consumption of inadequate soy infant formula, was found in in Israel (Fattal-Valevski A, Pediatrics. 2005 Feb;115(2):e233-8.) Young infants < 6 mo of age consuming the proposed follow-up formula for young children (12-36 months) would be similarly at risk, since thiamin is not required, nor are numerous other nutrients in the composition currently under discussion (including niacin, vitamin B6, vitamin E, vitamin K, niacin, folic acid, etc.) By naming the 2 products being considered under this standard with clearly different names, this is less likely to occur.

It is important to note (See Table 1), attached, that the follow-up formula for young children (12-36 months) includes fewer proposed nutrients (13) than the 32 suggested in the GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN CAC/GL 8-1991.

Table 1: Essential compositional requirements in Codex Standards per 100 kcal

Nutrients	**FUF 1987**	**Infant Formula (1981,Rev.2007) (See FUF for older infants unless figure noted**		**FUF for Older Infants proposed 2016**			**FUF Young children Proposed 2016**		**Fortified Complementary foods (2013)**
	Min/max	**Min**	**Max (GUL)**	**Min**	**Max**	**GUL**	**Min**	**Max (GUL)**	**Min**
Energy (kcal/100 mL)	60/85			60	70		45 or 60		4 kcal/per gm dry
Protein (g/100kcal)	3/5.5	**1.8**	3.0	[1.8] [1.65]	[3.5] [3.0] [2.5]		***	***	6% of energy min. 15% (max)
Fat (g/100kcal)	3/6			4.4	6.0		3/3.5/4.4		20% of energy
LA (mg/100kcal)	same		1400 (GUL)	300	-		***	***	333
ALA (mg/100kcal)	**None**			50	NS		None	none	none
DHA (% of fatty acids)**	**None**	None		[-] [0.3]		0.5	***	***	none
Carbohydrates (g/100kcal)				9.0	14.0		7.5/9.0	14	none
Vitamin A (µg RE/100 kcal)	225(Max)	60		75	180		[75]/60/50	225/180	67
Vitamin D (µg /100 kcal)	same			1.0	3.0		***	***	.8
Vitamin E (mg α-TE/100 kcal)	.7.NS			0.5		5.0	NS	NS	.8
Vitamin K (µg/100 kcal)	4/NS	**4**		[1] [4]		27	NS	NS	2.5
Thiamine (µg/100 kcal)	40/NS			60		300	NS	NS	83
Riboflavin (µg/100 kcal)	60/NS			80		500	***	***	83
Niacin (µg/100 kcal)	250/NS			300		1500	NS	NS	1000
Vitamin B_6 (µg/100 kcal)	45/NS			35		175	NS	NS	83
Vitamin B_{12} (µg/100 kcal)	.15/NS			0.1		1.5	***	***	.2
Pantothenic acid (µg/100 kcal)	300/NS			400		2000	NS	NS	333
Folic acid (µg/100 kcal)	4/NS			10		50			25
Vitamin C (mg/100 kcal)	8/NS			[4] [10]		70	***	***	**5**
Biotin (µg/100 kcal)	/NS			1.5		10	NS	NS	1.3
Iron (mg/100 kcal)	Same	.45		1.0	2.0		1	2/3GUL	1
Calcium (mg/100 kcal)	90/NS		140 (GUL)	50		180	90/50/200	180/NS	83
Phosphorous (mg/100 kcal)	60/NS			25		100	NS	NS	77
Magnesium (mg/100 kcal)	6/NS			5.0		15	NS	NS	10
Sodium (mg/100 kcal)	20/85			20	60		***	***	**none**
Chloride (mg/100 kcal)	55/NS			50	160		NS	NS	none

Potassium (mg/100 kcal)	80/NS			60	180		NS	NS	none
Manganese (mg/100 kcal)	**None**			1.0		100	NS	NS	77
Iodine (µg/100 kcal)	5/NS			10		60	NS	NS	15
Selenium (µg/100 kcal)	**None**			2.0		9.0	NS	NS	2.8
Copper (µg/100 kcal)	**None**			35		120	NS	NS	.1
Zinc (mg/100 kcal)	.5/NS		1.5	0.5		[1.0] [1.5]	***	***	.7

Values under consideration in square brackets [x] *** not yet decided but to be required in FUF; NS not specified ; Only different values than those given for FUF for Older Infants are shown; To calculate the nutrients recommended in the Formulated Complementary Food standard (vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 50% of INL98), we took 50% of the nutrients shown in Formulated Complementary Food Standards' Table, assuming that is what should be contained in 300/kcal and other levels in this table.

It is important to also consider that since the follow-up formula for young children being considered is currently proposed to mandatorily require the addition of fewer nutrients, it is likely to be less costly to manufacture and therefore could be sold at lower cost than infant formula or follow-up formula for older infants. The lower cost could lead poor families to purchase an inappropriate and potentially detrimental product for feeding of their infant.

These are important public health issues that must be discussed and be considered by the eWG and CCNFSDU full committee.

We propose the following revised wording:

9.1 The Name of the ~~Food~~ Product

9.1.1 The name of the ~~food~~ Products shall be "Follow-up Formula for Older Infants" and "Fortified Milk for Young Children. ~~In addition thereto, any appropriate designation may be used in accordance with national usage.~~

9.1.2 Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula for Older Infants based on milk" or "Fortified Milk for Young Children" depending on the formulation.

Section **9.5** needs to be revised to take into account the proposed new name for the 2 products, as suggested below:

9.5 Information for Utilization

9.5.1 Directions as to the preparation and use of the ~~food~~ product, and its storage and keeping after the container has been opened shall appear on the label.

9.5.2 The labelling of a Follow-up Formula for Older Infants and Fortified Milk for Young Children shall include a statement that ~~Follow-up Formula~~ they shall not be introduced before the 6th month of life.

9.5.3 Information that older infants and young children fed Follow-up Formula for Older Infants or Fortified Milk for Young Children shall receive other foods in addition to the ~~food~~ product shall appear on the label.

Section **9.6** needs to be revised to include language from the Infant Formula Standard CODEX STAN 72 – 1981 since these products are also breastmilk substitutes.

9.6 Additional Labelling Requirements:

9.6.1 Labels should not discourage breastfeeding. Each label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) the statement "Breast milk is the best food for your baby" or a similar statement as to the

superiority of breastfeeding or breast milk;

c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of the product.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the product, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, fortified milks for older children and formula for special medical purposes.

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

Answer:

It is critical to consider the latest WHA resolution 69.9 adopted in May 2016 that refers to the WHO Guidance on ending the inappropriate promotion of foods for infants and young children. Recommendation 2 of the guidance states:

"Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products."

Since both products included in this standard are clearly breast-milk substitutes, wording from the Infant Formula Standard referencing the International Code of Marketing of Breast-milk Substitutes must be included in the Scope of this standard. Therefore, the Title, the Scope, the Definitions, and the Names used for the 2 products, as discussed above, must be changed.

We propose the following changes to the Title of Standard:

CODEX STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND FORTIFIED MILKS FOR YOUNG CHILDREN

We propose the following changes to 1. Scope:

This standard applies to the composition and labelling of follow-up formula for older infants and fortified milks for young children.

In addition, as WHA 69.9 has now provided clarity that these products are breast-milk substitutes, we propose that a 1.1 and 1.2 should be added to the Scope.

The proposed 1.1 is taken from 1.1 of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72 – 1981) and slightly modified and should read:

1.1. This applies to follow-up formula for older infants and fortified milks for young children in liquid or powdered form intended for use~~, where necessary,~~ as a substitute for human milk in ~~meeting~~ helping to meet the normal nutritional requirements of older infants and young children;

The proposed 1.2 is taken from 1.4 of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72 – 1981) modified to include the wording of WHA 69.9 should read:

1.2 Application of this Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981) and subsequent resolutions adopted by the World Health Assembly related to the Code, the Global Strategy for Infant and Young Child Feeding, World Health Assembly resolution WHA 54.2 (2001) and WHA 69.9 (2016).

Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up

Formula, and if so, how and where? For example in the Scope and Labelling sections.
Answer: Yes, references should be made to relevant WHA resolutions as these have been adopted at the global level and give substance to the text contained in the Codex Standard and Codex is required to base its standards on relevant resolutions of the mother bodies, in this case WHO's decision making body. Thus we above we strongly believe that the Scope should include reference to WHA resolutions and propose the addition of a 1.2 to the Scope taken from 1.4 of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72 – 1981) modified to include the wording of WHA 69.9 that reads (see previous comment): 1.2 Application of this Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981) and subsequent resolutions adopted by the World Health Assembly related to the Code, the Global Strategy for Infant and Young Child Feeding, World Health Assembly resolution WHA 54.2 (2001) and WHA 69.9 (2016).
Please comment on how CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF./7 Rev 1) for 'Ending inappropriate promotion of foods for infants and young children' and the associated technical guidance document. Please be specific in your response and comment on what aspects of the resolution or guidance should be captured within the Standard for Follow-up Formula and within what subsection it should be reflected.
Answer: CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF./7 Rev 1) for 'Ending inappropriate promotion of foods for infants and young children' and the associated technical guidance document as this is a resolution adopted by the decision-making body of WHO that is attended by delegations from all WHO Member States and focuses on a specific health agenda. As the WHO is one of the mother bodies of Codex Alimentarius, its resolutions must be taken up into Codex Committee's text. The guidance that forms part of WHA resolution 69.9 must be incorporated into this standard while it is open for review. The standard must therefore clearly state that the 2 products included in this standard are now considered to be breast-milk substitutes and must therefore follow the International Code of Marketing of Breast-milk Substitutes and subsequent resolutions. It would be totally unacceptable for this standard not to ensure that it is in line with the decision made by the World Health Assembly. Just as the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72 – 1981 has recognised the International Code of Marketing of Breastmilk Substitutes and that the products under the standard must comply, so to must this standard based on WHA69.9. Therefore, as with the Infant Formula standard, the applicable place is within the Scope of the standard, where we recommend the text should read: 1.1 This applies to follow-up formula for older infants and fortified milks for young children in liquid or powdered form intended for use, as a substitute for human milk in helping to meet the normal nutritional requirements of older infants and young children. 1.2 Application of this Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981) and subsequent resolutions adopted by the World Health Assembly related to the Code, the Global Strategy for Infant and Young Child Feeding, World Health Assembly resolution WHA 54.2 (2001) and WHA 69.9 (2016) It is also the reason that 9.6 must be replaced in the standard to include the following from the Infant Formula standard: 9.6 Additional Requirements: ~~The products covered by this standard are not breast-milk substitutes and shall not be presented as such.~~ 9.6.1 Labels should not discourage breastfeeding. Each label shall have a clear, conspicuous and easily readable message which includes the following points: 9.6 Additional Labelling Requirements: 9.6.1 Labels should not discourage breastfeeding. Each label shall have a clear, conspicuous and easily readable message which includes the following points: a) the words "important notice" or their equivalent; b) the statement "Breast milk is the best food for your baby" or a similar statement as to the

superiority of breastfeeding or breastmilk;
c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of the product.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the product, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, fortified milks for older children and formula for special medical purposes.

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

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

Answer: This statement needs to be taken out of the standard and the following wording added instead:

The labelling requirements in 9.6 of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72 – 1981) need to be incorporated into the standard as a direct consequence of 69.9. Both products should follow the International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly resolutions, including 69.9. Therefore, 9.6 should be deleted from the standard and the following text (also suggested above) should be added:

9.6 Additional Requirements:

9.6.1 Labels should not discourage breastfeeding. Each label shall have a clear, conspicuous and easily readable message which includes the following points:
a) the words "important notice" or their equivalent;
b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk;
c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of the product.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the product, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, fortified milks for older children and formula for special medical purposes.

Aside from WHA 69.9 and the associated guidance, it is clear from research that these products are positioned and promoted as breast-milk substitutes. See the research under taken by the Helen Keller Internationals Assessment and Research in Child Feeding (ARCH) Projects results published in a supplement of the Maternal and Child Nutrition journal (April 2016 – Volume 12, Supplement 2), specifically the Pereira et al. article 'Cross-sectional survey shows that follow-up formula and growing-up milks are labelled similarly to infant formula in four low and middle income countries (available open source access at http://onlinelibrary.wiley.com/doi/10.1111/mcn.12269/epdf and attached to this submission).