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: _SOUTH AFRICA_____

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	**X** 1.65 g /100 kcal 0.39 g /100 kJ

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

Summary:
Recent estimates of protein requirements are lower than previous estimates, primarily as a result of changes in the reference body weights that were previously used. In addition, several national and regional surveys of dietary protein intakes in older infants (6-12 months of age) have identified that protein intakes in this age group are adequate for the majority of infants and may even be excessive.

Scientific justification:
The WHO/FAO/UNU review of protein requirements calculated protein requirements based on the factorial method which takes into consideration protein required for maintenance and growth (WHO/FAO/UNU 2007). The calculations are based on maintenance of requirements of 0.66 g/kg bodyweight per day and a protein efficiency utilization of 58%. In the recently published "Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union", EFSA adopted the same approach (EFSA 2013).

Several national and regional surveys of dietary protein intakes of older infants and young children

have been conducted. The results of these surveys have consistently identified that protein intakes in this age group are adequate for the majority of infants and young children, and may even be excessive.
In developed countries, protein requirements are generally met and even exceeded, even in the poor countries (Agostoni 2006).

Protein excess in industrialized countries has been reported to be significantly high during the complementary feeding, due to high consumption of home-made produced complementary foods, cow's milk and low-fat dairy products. Mean intakes in young children ranged from 20 g (Philippines FNRI) to 60g (Australia DOHA 2008) per day – two to six times higher than the WHO/FAO/UNU safe intake level (reported in CX/NFSDU 14/36/7 2014).

In Uganda, data were presented as percentiles and highlighted that even at the 5th percentile, intakes were twice those recommended by WHO/FAO/UNU (Harvey 2010).
A recent study conducted in France showed that infants and young children receive too much protein. Compared to the requirements, the average protein intake is already excessive at 6 months of age (17.8 g/day) and even higher in toddlerhood (35-42 g/day) (SFAE 2014). The same conclusions apply to other surveys conducted in infants in Asia, where protein intakes ranged from 14 to 50 g/day (Poh 2013, FNRI 2008, Nguyen 2013 and Rojroongwasinkul 2013, Sandja 2013).

EFSA reports that "protein intakes in infants and young children living in Europe were above the average requirements in all surveys and all population groups and were around 9 E% (% of total energy) in infants aged from 0 to < 6 months, 10 to 15 E% in infants in the second half of the first year of life and 12 to 19 E% in young children", compared to 7 E% in mature human milk (EFSA 2013, 2014). Several nationally and regionally representative surveys of dietary protein intakes of older infants and young children show that these conclusions are not only true for Europe, but also globally (e.g. Thailand, Mexico, Australia, Malaysia) (CX/NFSDU 14/36/7 2014).

During the complementary feeding period, not only FUF but also other foods contribute to the protein intakes. Consequently, it is challenging to identify how much should be provided by FUF and by other foods. Recently, Thorisdottir *et al* described intakes of various animal and vegetable proteins of 12 months old infants. Protein intake was 3.0 g/kg body weight at 12 months and 41% of the total protein intake came from dairy products (including formulas) (Thorisdottir 2014). In the Feeding Infants and Toddlers Study (FITS 2008), the average protein intake for infants aged 6 to 11 months was 22.4g/d while the dietary reference intake is 11g/d (Butte 2010). The percent contribution of infant formula to total protein intake was 34.8% for infant formula and 8.8% for breast milk (unpublished data).

High protein intake in excess of requirement has no benefit for infants and is considered as burden for metabolism since extra protein intake needs to be oxidized or excreted and hence should be avoided. Even if WHO/FAO/UNU report stated that there is no risk to individuals with excessive intakes considerably higher than the safe intake levels (WHO/FAO/UNU 2007), they have recently acknowledged that current follow-up formula products lead to higher protein intakes than those recommended by WHO and FAO for adequate growth and development (WHO 2013).
No upper limit has been set by the WHO/FAO for protein and the effects of a diet habitually high in protein intakes are unclear. However there are some studies which are suggestive that excessive protein intakes in early childhood may be associated with differences in growth and obesity risk later in life (CX/NFSDU 14/36/7 2014).
For all the reasons mentioned above (protein content of human milk, protein requirements, Early Nutrition Academy recommendations on compositional requirements of follow-up formula and safety and suitability of the proposed protein level by clinical evidence), South Africa supports a decrease of the minimum value for protein for follow-up formula for older infants with cow's milk protein at 1.65g/100kcal based on a good protein quality with a footnote 6 requiring clinical evidence of safety and suitability of follow-up formula with a protein content between 1.65g/100 kcal and 1.8g/100 kcal.

Maximum

x 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:

The scientific evidence is inconclusive to support an exact maximum for protein levels in follow-up formula

for older infants, nor an upper limit for protein for older infants, as acknowledged by both EFSA (2014) and the WHO/FAO (2007). The maximum proposed protein limit of 3.5 g protein/100 kcal is safe and suitable consumption by older infants, has a long history of apparent safe use and has been globally marketed since the origin of the Codex Standard for Follow-up Formula (Codex STAN 156-1987).

Footnote 3

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

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

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

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

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

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

In addition, Annex I of the Codex Standard for Infant Formula describes the levels of essential and semi essential amino acids expressed per g of nitrogen, per g of protein and per 100kcal. The average level of an amino acid (mg per g of nitrogen) from each study described in Annex I was used to calculate the corresponding amino acid content per 100 kcal of an infant formula with the minimum protein content of 1.8 g/ 100 kcal accepted in this Standard (mg amino acid/g nitrogen in breast-milk divided by the nitrogen conversion factor of 6.25 and multiplied by 1.8). If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for follow-up formula for older infants, new calculations should be made using a factor of 1.65 instead of the factor of 1.8 currently used in Annex I of the Codex Standard for Infant Formula.

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	***x*** Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated

Please provide justification for your response.

South Africa considers that intact as well as hydrolysed protein has been safely used as a protein source in follow-up formula for older infants. Indeed several studies have demonstrated that formulas based on hydrolysed protein support adequate growth of during infancy (Berseth, 2009; Vandenplas, 2016).
As such we consider the footnote 6 should also encompass the scientific substantiation of the nutritional suitability and the safety of use of hydrolysed protein when used in follow-up formula for older infants at low level.

The footnote should read:
"Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated **when needed.**"

References

Berseth CL, Mitmesser SH, Ziegler EE, *et al.* (2009) Tolerance of a standard intact protein formula versus a partially hydrolyzed formula in healthy, term infants. *Nutrition Journal*, 8:27.
Vandenplas Y, Alarcon P, Fleischer D, *et al.* (2016) Should partial hydrolysates be used as starter infant formula? A working group consensus. *Journal of Pediatric Gastroenterology and Nutrition,* 62: 22–35.

Regarding formulas based on **intact/non-hydrolysed** protein please note that your responses to these questions do not imply that you support a minimum of 1.8 g/100 kcal or 1.65 g/100 kcal. They will be used to refine the wording in square brackets if the eWG cannot come to agreement on a minimum value. Please state whether you support the proposal to amend the reference these types of formulas to **intact milk protein**.		
intact milk protein	**x** non-hydrolysed milk protein	
Please provide justification for your response. For the sake of clarity and as better defined than intact milk protein, we propose to align with Codex Standard for Infant Formula (CODEX STAN 72 – 1981 , rev.2007) and use the wording Non hydrolysed protein.		
Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required forany formulas based on intact/non-hydrolysed milk protein?		
x 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. South Africa is of the opinion that all formulas containing a protein content between 1.65 and 1.8g/100kcal require clinical evaluation. Follow-up formula containing a protein level between 1.8g and 2.0g/100kcal do not require clinical evaluation as these formulas had been reviewed recently by EFSA (EFSA 2014) and EFSA concluded that the scientific data is sufficient to prove the safety of all formulas (infant and follow-on) manufactured from intact milk protein with a protein content higher than 1.8g/100kcal. However, in order to confirm their safety and suitability IFA recommends that formulas containing protein between 1.65 and 1.8g/100kcal should be clinically evaluated prior to placing on the market. References EFSA (2014) Scientific opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*, 12(7):3760.		
If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for formula based on intact/non-hydrolysed milk protein, do you support the recommendation that the minimum protein level which requires clinical evaluation is placed in the footnote, rather than in the table? See **Error! Reference source not found.**above		
Yes	***x*** 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: South Africa supports a minimum vitamin K level at 4 mg/100 kcal based on the totality of scientific data available to date regarding safety of use and nutritional suitability and a GUL of 27 mg/100 kcal The nutritional suitability and safety of use of this minimum vitamin K level (4 mg/100 kcal) for follow-up formulas for older infants was most recently substantiated by the ENA proposal for the			

compositional requirements for follow-up formula for older infants (Koletzko, 2013).

References

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

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	**x**☐ 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:

South Africa support a minimum vitamin C level of 10mg/100 kcal. In the formula study we conducted in South Africa vitamin C was found to be low after storage and preparation of formula.

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:

South Africa support the GUL zinc level of 1.5 mg/100kcal.

We are of the opinion that having a GUL at 1.0mg/100kcal would potentially limit zinc fortification, which is not desirable. Zinc deficiency is still an important cause of morbidity in developing countries and is reported to account for 1.7% of deaths in children less than five years of age (Black 2013. This has also been observed in low income countries like Cameroon or Uganda (CX/NFSDU 14/36/7).

The statistical analysis of actual zinc levels suggests that at a GUL of 1.0 mg/100 kcal as proposed by the 37th CCNFSDU, several batches would exceed the GUL. Therefore a higher GUL at 1.5 mg/100 kcal

would be appropriate given the fact that GUL for zinc is set in the Codex Standard for Infant Formula at 1.5 mg/100 kcal and that there are actual data to support the history of apparent safe use at a level of 1.5 mg/100 kcal. A higher GUL, such as the one provided for in for infant formulas, would encompass the technological aspects and the history of apparent safe use.

Optional Ingredients: DHA

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

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.		
x☐ 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 is used for acidification, L(+) lactic acid cultures are inactivated during the production process and are a food additive from a Codex perspective (or a processing aid depending on definitions applied in national legislation). So saying, given the different interpretations of the current 3.3.2.4 in Codex STAN 156-1987, and apparent from the feedback received by the eWG on this topic, it could be helpful to clarify this in section. If used for supplementation of product with viable organisms, the addition is for the purpose of conferring other outcomes that may be broadly categorized as 'for a nutritional purpose' and fits within the framework for optional ingredients.		
If you consider that standard should allow for both types of addition, please indicate if you think that this should be captured within 3.3.2.4, or as two separate clauses within the Optional Ingredients Section (Section 3.3.2).		
South Africa is of the opinion that both types of addition should be addressed in two separate clauses within the Optional Ingredients section (section 3.3.2) -Section 3.3.2.4 should be kept for acidification: Only L(+) lactic acid producing cultures maybe used -Under the section 3.3.2, there is a need to create a sub-section which can be 3.3.2.5 and would stipulates that "Other bacterial strains may be used when demonstrated safe and suitable in accordance with the		

general principles that are listed in the sections 3.3.2.1 and 3.3.2.2 relative to optional ingredients in the Standard".
Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.
x☐ 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: Cultures added to any infant formula must met the criteria of safety (including non-pathogenicity) and suitability, evaluated and demonstrated by generally accepted scientific evidence.

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 core composition**
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: **All the mandatory composition principles should be met. There is a need for delienation of this follow-up formula for older infants and older young children. A principle to diffeentiate between these two products must be included (e.g. naming of these products).**
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

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nutrients. If you do not support this approach, please present an alternative approach with justification.

Answer:
Please provide justification for your answer:

South Africa does not support the proposed approach for the 'voluntary addition of nutrients'. Other additional nutrients must follow the principle of optional ingredients in other standards. This could create a loophole and encourages the industry to add other nutrients for marketing purposes.

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:
No

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:
Stick to the existing fundamental principles of optional ingredients throughout this standard.

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

Answer:
Please provide justification for your answer:

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

Answer:
Please provide justification for your answer:
South Africa agree with the Chairs that the third bullet must be deleted. Stick to the fundamental principles of optional ingredients throughout this standard.

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: **South Africa is concerned that setting minimums and maximums for protein and fat may allow excessive levels of carbohydrates which could lead to a product with high sugar content. A maximum should be set for free sugars in these products.**

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?		
x☐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. South Africa is of the view that dietary fat in complementary foods of young children in developing countries is limited, so the minimum should not be lower than that found in full fat cow's milk. While children over 24 mo of age may not need additional energy which could pose a risk of overweight and obesity, the focus should be 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
Considering the eWG's varied views, are minimum and maximum requirements necessary? If so, please state your preferred approach on how to establish protein requirements?
Please provide justification for your answer
Should there be requirements for protein quality? If so how this might be achieved? Please consider both the current Follow-up formula standard, and proposals within the draft standard for older infants.
Please provide justification for your answer Protein requirements have been recently estimated to be lower than previous estimates primarily as a result of changes in the reference body weights used. Additionally several dietary surveys of protein intakes have identified that average protein intakes are generally adequate for the majority of young children (12-36 months), with average intakes typically exceeding requirements (CX/NDSDU 14/36/7). We recommend that the lower minimum protein level to be in line with the WHO/FAO/UNU Requirements.

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	**x**☐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 **Children of these age groups are still growing and may require additional fat since it is supplied in limited amounts in most of the diets in developing countries.**	
Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?	
x☐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	

Essential Fatty acids

Lipids	
Based on the eWG recommendation to give consideration to the fatty acid profile of follow-up formula for young children, including maximum levels for trans fat, and noting the levels in full fat and reduced fat cows' milk, please state your preferred levels (with justification) as below: Should levels for linoleic acid, α-linolenic acid and phospholipids be established for follow-up formula for young children? Please stipulate what these levels should be; min, max, GUL.	
Please provide justification for your answers. South Africa is of the opinion that there is insufficient evidence with regard to the intake of LA in young child's diet. It is not necessary to include minimum and maximum levels.	
Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?	
x☐ 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 forlauric and myristic acid be established for follow-up formula for young children?	

☐ Yes Should this level be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk? ☐ Yes ☐ No ☐ Alternative, please specify and provide justification for your answer.	**x**☐ No
Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
x☐ Yes Please state what the maximum level should be, and provide justification for your answer. **Trans fat must not be included in the follow-up formula. We recommend a maximum of 0.5%**	☐ 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. **Yes**	

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	**x** 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:	
If limits are established for sugars, is there a need to also set a maximum/GUL for total available carbohydrates?	
x☐ Yes	No
Please provide your rationale: **It is essential that maximum be specified to avoid high sugar content products marketed and consumed by 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:	
If you support establishing a maximum/GUL, do you support 14 mg/100 kcal (3.3 mg/100 kJ)?	
Yes	**x** No (please specify your alternative).
Please provide your rationale: **The proposed amount is too high. The WHO recommendations of free sugars should be taken into consideration when establishing a maximum**	

Carbohydrates footnote		
Free sugars While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.		
Proposed Codex FUF-OI Standard Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.	IEG 2015 Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	**x** An alternative level (please specify)
Please provide your rationale: We prefer that sugar and fructose not be added to these products and ensure that recommendations made are in line with the WHO provisions.		
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 infollow-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 **x** 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		
x 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	**x** 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:			
x☐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		☐Alternative value, please specify	

200 mg/100 kcal	
Please provide justification for your answers. FAO (2013) minimum and maximum calcium density is 147-194mg/100kcal. The minimum and maximum (FAO, 2013) calcium levels in whole milk translate to approximately 55-72% of the NRV for calcium. As calcium and protein levels are linked, and technical feasibility issues may be encountered when formulating higher calcium levels in low protein products. It will be important to define protein levels before the minimum for calcium can be established.	
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.	**x**☐Alternative value, please specify

Calcium		
Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included? Ratio calcium/phosphorus		
Min	**Max**	
1:1	2:1	
Yes		**x** No
Please provide your rationale: Various sources phosphorus exist such as the in the diet of young children. Therefore maintaining the Ca/P ratio may not be valuable since other sources of phosphorus in children's diets cannot be controlled.		

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	**x** WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ	
Please provide your rationale: **A minimum which corresponds to 15% of RNI established by FAO/WHO would be the preferred minimum value.**			
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	
x 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: **This value would ensure that Vitamin A does not reach toxicity levels**	
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.	
x Yes	No

Vitamin D

Vitamin D	
Do you support that mandatory addition of vitamin D to follow-up formula for young children?	
x☐Yes	☐No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: **South Africa supports the value of 1.5µg/100kcal**	
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: **We support a maximum of 4.5µg/100 kcal, which corresponds to 3 times the minimum level seems to be appropriate**	

Zinc

Zinc	
Do you support that mandatory addition of zinc to follow-up formula for young children?	
x☐Yes	☐No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: **Due to high zinc deficiencies in developing countries, we'll support its addition to the FUF**	
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer:	

Vitamin C

Vitamin C	
Do you support that mandatory addition of vitamin C to follow-up formula for young children?	
X☐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 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: We support mandatory addition of vitamin C. We recommend a minimum level of 4.5mg/100kcal to be in line with 15% of the FAO/WHO DRI.	

Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
x☐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 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:	

Riboflavin

Riboflavin	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
x☐Yes	☐No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: **We recommend a minimum level of 75µg/100kcal, which is in line with the 15% of the FAO/WHO DRIs.**	
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:	

Sodium

Sodium	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
x☐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:
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:

SCOPE & LABELLING

Scope & Labelling When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.
Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?
Please provide justification for your answer. **Yes** **There is a need for different approaches in terms of labelling with specific reference to the composition criteria of these two products.** **South Africa believe that the protection of consumers with regard to the labelling of these products must come first. We propose that different names be given to these products. We are concerned that the use of the word "formula at the end of these products 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".** **Therefore these products will not meet all the nutritional requirements, specifically for children from 12 to 36 months. The use of the word "formula" could mislead the mothers who might associate these products with infant formula.**
Are there any labelling areas where different provisions may be required for the two age groups?
Please provide justification for your answer. **These two products must have distinct different names to avoid confusing mothers and caregivers. They must be color-coded differently and clear messages must be reflected on labelling with specific reference to their intended 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: **A reference to the provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant WHA resolutions should be made. The 69th WHA determined that all the products marketed for children up to 36th months - whether they conform to essential compositional requirements of infant formula or not - replace breastmilk and therefore their labelling and marketing should be governed by the International Code of Marketing of Breast-milk Substitutes and subsequent relevant WHA resolutions.**
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** **South Africa support a reference to WHA resolutions and other relevant documents. We**

propose the following wording which should form part of the scope and is in line with the current CODEX STAN 72 - 1981, ERV. 2007.

"The application of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the WHO Global Strategy for Infant and Young Child Feeding and relevant World Health Assembly resolutions 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:

South Africa propose the inclusion of the following aspects of the resolution within the standard:

Recommendation 3. Foods for infants and young children that are not products that function as breast-milk substitutes should be promoted only if they meet all the relevant national, regional and global standards for composition, safety, quality and nutrient levels and are in line with national dietary guidelines. Nutrient profile models should be developed and utilized to guide decisions on which foods are inappropriate for promotion. Relevant Codex standards and guidelines1 should be updated and additional guidelines developed in line with WHO's guidance to ensure that products are appropriate for infants and young children, with a particular focus on avoiding the addition of free sugars and salt.

Recommendation 4. The messages used to promote foods for infants and young children should support optimal feeding and inappropriate messages should not be included. Messages about commercial products are conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Irrespective of the form, messages should always:

• include a statement on the importance of continued breastfeeding for up to two years or beyond and the importance of not introducing complementary feeding before 6 months of age;

• include the appropriate age of introduction of the food (this must not be less than 6 months);

• be easily understood by parents and other caregivers, with all required label information being visible and legible.

Messages should not:

• include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages);

• include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast-milk, or that suggests that the product is nearly equivalent or superior to breast-milk;

• recommend or promote bottle feeding;

• convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

Recommendation 5. There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children.

• The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).

• Companies that market breast-milk substitutes should refrain from engaging in the direct or indirect

promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).

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:

South Africa support the amendment to section 9.6 to be in line with the Recommendation 2 of the WHA 69. 9, which reads as follows:

" 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".