REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156-1987)
(Chaired by New Zealand and co-chaired by Indonesia and France)

Second Consultation Paper
Submitters Response Form

June 2016

Please respond by **19th July 2016**
To: Jenny.Reid@mpi.govt.nz; Alice.STENGEL@dgccrf.finances.gouv.fr; codexbpom@gmail.com

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

Name of Member Country/Organisation: **NORWAY**

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:

In line with EFSA 2014 and the EU Regulation on Infant Formula and Follow-On Formula, at this stage, we continue to support a minimum of 1.8 g/100 kcal.

We support the proposal of the Chairs to await further details from the EFSA review on the safety and suitability of consumption of lower protein formulas containing at least 1.61 g protein/100 kcal, to inform further discussion on the minimum content of protein in follow-up formula for older infants.

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:

Norway still supports a maximum of 2.5 g protein/100 kcal, which is in line with EFSA.

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)[1].

With a representative caloric intake of 500 kcal/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. In addition to this, complementary feeding would also provide some protein.

Several nationally and regionally representative surveys of dietary protein intakes of older infants and young children have been conducted globally, and 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 addition some studies suggest that excessive protein intake in early childhood may associated with differences in growth and increased obesity risk later in life. Even though there is no conclusive evidence of this, we are of the opinion that this implies a lower max limit for protein, in order to avoid potential risks associated with high protein intakes. According to EFSA, there is no evidence for a physiological need for protein intakes at amounts of 3.0 g/100 kcal.

In summary, there is no need to exceed a maximum limit of 2.5 g/100 kcal, and high protein intakes should be avoided in order to reduce possible associated risks.

[1] Report of the eWG FUF 2014 (CX/NFSDU 14/36/7)

Footnote 3
Refers to the requirements of essential and semi-essential amino acids in follow-up formula:
[3)] For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk as defined in Annex I); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.
At present the draft standard does not contain an Annex I, please indicate whether you support inserting Annex I of the Codex Standard for Infant Formula of if you consider that further work is required.

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

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

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.

EFSA proposed a minimum amount of protein of 1,8 g/100 kcal and did not require clinical evaluation of *non-hydrolysed milk protein*. Norway suggests awaiting the EFSA review on the safety and suitability of consumption of lower protein formulas containing at least 1.61 g protein/100 kcal in follow-up formulas, before deciding whether clinical evaluation is needed for a lower minimum amount.

Norway supports a requirement stating that all formula based on *hydrolysed protein* should be clinically evaluated. EFSA (2014) has emphasised that the safety and suitability of formula containing protein hydrolysates, including their minimum protein content, has to be established by clinical studies.

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.

EFSA proposed a minimum amount of protein of 1,8 g/100 kcal and did not require clinical evaluation of *non-hydrolysed milk protein*. Norway suggests awaiting the EFSA review on the safety and suitability of consumption of lower protein formulas containing at least 1.61 g protein/100 kcal in follow-up formulas, before deciding whether clinical evaluation is needed for a lower minimum amount.

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 **Feil! Fant ikke referansekilden.** 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:

Norway continues to support a minimum vitamin K content of 1 µg/100 kcal, which is based on the EFSA opinion from 2014 and which is in line with the new EU Regulation on Infant Formula and Follow-On Formula.

The EFSA recommendation is based on the recommendation that a vitamin K intake of 5 µg per day is adequate for the majority of young infants (0-6 months), and that the nutrient composition of infant formula is generally sufficient for older infants as the energy and nutrient intakes from complementary foods will compensate for the higher requirements of older infants. NNR 2012[1] refers to that new-borns should routinely be

given vitamin K to avoid haemorrhage during the neonatal period, and that oral prophylaxis should be continued for the first three months. We are not aware of haemorrhagic problems in healthy children from 6 months, and therefore do not consider haemorrhagic problems as a justification for the minimum amount of vitamin K in the age group of 6-12 months.

[1] Nordic Nutrition Recommendations 2012

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:

Norway supports a minimum vitamin C content of 4 mg/100 kcal, which is based on the EFSA opinion from 2014 and is in line with the new EU Regulation on Infant Formula and Follow-On 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:

In accordance with the EFSA Panel (2014) Norway supports a minimum zinc content in FUF based on milk protein or containing protein hydrolysates of 0.5 mg/100 kcal (0.12 mg/100 kJ). For FUF containing ISP a minimum content of 0.75 mg/100 kcal (0.18 mg/100 kJ) is supported, because zink in soy milk may be less available due to phytic acid (that may reduce zinc absorption).

Norway continues to be in favour of a maximum of 1.0 mg zinc/100 kcal, and a maximum of 1.25 mg zinc/100 kcal for follow-up formulas based on soy protein isolates, which is in line with the new EU Regulation on infant formula and follow-on formula.

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.			
☒ Yes		☐ No	

Norway supports a minimum requirement for DHA in the standard, and can accept a minimum value of 0,3 %, which nearly corresponds to the EU value. A minimum value should be established based on DHA being considered conditionally essential.

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:

Norway considers that live microorganisms should not be added to follow-up formula unless safety and suitability is fully demonstrated for infants.

With reference to several scientific publications[1], the safety and suitability of follow-up formula supplemented with lactic acid producing cultures is not fully demonstrated. Due to the fact that infants is a specific vulnerable group, and that there still is scientific uncertainty whether there are long-term negative effects, we consider a cautious approach appropriate.

Lactic acid-producing bacterial cultures can be used as processing aids to acidify products. EU Regulation 1333/2008 applies to additives, and does not apply to processing aids. Therefore, the note in Annex II, only *informs* that non-pathogenic L(+)-lactic acid producing cultures may be used for the manufacture of acidified milks. Use as a processing aid means that the bacterial cultures are not consumed as a food by itself, but is used to fulfil a technological purpose (acidifying), and may result in the unintentional but technically unavoidable presence in the final

product of residues, provided they do not present any health risk and do not have any technological effect on the final product.

Norway can accept that the standard allows for the use of L(+) lactic acid-producing cultures for the purpose of acidifying formula, but only provided that the acidified final formula product does not contain any significant amounts of viable L(+) lactic acid-producing bacteria and that these residual amounts do not represent any health risk.

[1] See the Norwegian input to the first eWG consultation, and the summary in CCNFSDU 2016 2nd Consultation Paper, chapter 3.9.

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:

With reference to chapter 3.9 in CCNFSDU 2nd Consultation Paper and our former input to the first eWG consultation, we would like to emphasize that there is insufficient data and further evaluation of safety in long-term studies is needed. The early microbial composition of the human gastro-intestinal tract can have long-lasting functional effects. Therefore, considering the recently-found connection between the gut microbiome and a number of disorders appearing later in life, we again recommend a cautious approach. We consider that live microorganisms should not be added to follow-up formula unless safety and suitability is fully demonstrated for infants.

As described above, we can accept use of L(+) lactic acid-producing bacterial cultures for the purpose of acidifying formula, but only provided that the acidified final formula product does not contain any significant amounts of viable L(+) lactic acid-producing bacteria and that these residual amounts do not represent any health risk.

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:

Should there be a minimum number of principles that each nutrient must meet in order for it to be considered part of the mandatory (core) composition, or requiring specific compositional parameters in follow-up formula for young children? Please state what this should be.

Answer:

Voluntary Nutrient Additions

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

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

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

QUESTION:

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

Answer:

Please provide justification for your answer:

QUESTION:

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

Answer:

Please provide justification for your answer:

Optional Ingredients

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

QUESTION:

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

Answer:

Please provide justification for your answer:

QUESTION:

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

Answer: *Please provide justification for your answer:*
QUESTION: Do you support deletion of the third bullet point for follow-up formula for young children?
Answer: *Please provide justification for your answer:*

Energy contribution from macronutrients

Energy contribution from macronutrients
Please provide comment and justification as to whether it is necessary to define specific macronutrient percentage contribution to overall energy.
Answer:

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		
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

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	
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	

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.	
Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?	
☐ Yes Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG? ☐ Yes ☐ No ☐ Alternative, please specify and provide justification for your answer.	☐ No
Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?	

☐ Yes Should this level be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk? ☐ Yes ☐ No ☐ Alternative, please specify and provide justification for your answer.	☐ No
Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
☐ Yes Please state what the maximum level should be, and provide justification for your answer.	☐ No
Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (*Commercially hydrogenated oils and fats shall not be used in follow-up formula*) also apply to follow-up formula for young children?	
Please provide justification for your answer.	

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:	
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:	
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	☐ 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 not exceed 20% of available carbohydrate.	☐ IEG 2015 Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	☐ An alternative level (please specify)
Please provide your rationale:		
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**	**Minimum**	**Maximum**	**GUL**
mg/100 kcal mg/100 kJ	[50] [90] [200] [18] [22] [24] [48]	[N.S.]	[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.	

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:
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.
Answer:

Vitamin C

Vitamin C
Do you support that mandatory addition of vitamin C to follow-up formula for young children?
☐ Yes ☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.
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:

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:	
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?	
☐ 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 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?	
☐ 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.
Are there any labelling areas where different provisions may be required for the two age groups?
Please provide justification for your answer.
Are you aware of further issues and/or evidence that need to be considered to inform the review of the scope and labelling section of the Codex Standard for Follow-up Formula? Please state the specific provisions within the Scope or Labelling section which would be informed by your response.
Answer:
Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up Formula, and if so, how and where? For example in the Scope and Labelling sections.
Answer:
Please comment on how CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF./7 Rev 1) for 'Ending inappropriate promotion of foods for infants and young children' and the associated technical guidance document. Please be specific in your response and comment on what aspects of the resolution or guidance should be captured within the Standard for Follow-up Formula and within what subsection it should be reflected.
Answer:
Taking into consideration relevant WHA resolutions and accompanying documents (section 6) and the role of product in the diet, are changes required to the current drafting of Section 9.6 of the current follow-up formula standard? Please consider both follow-up formula for older infants and for young children when answering this question and comment on whether there would may need to be different approaches for the different product categories. *9.6 The products covered by this standard are not breast-milk substitutes and shall not be presented as such.*
Answer: