

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: **ENCA**

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

We would like to express concern about the proposed naming of milks in this paper as 'FUF for older infants' and 'FUF for older young children'. We think this is extremely confusing and could lead to inappropriate milks being purchased. The key themes identified for decision making on standards for older young children (p33) included that there should be '*Less prescription: FUF for young children does not need to contain the full range of nutrients that are mandated for addition to product for older infants*' and therefore distinguishing between these two products is of paramount importance.

We would like to propose that if the distinction of milks from 6m-1y continues (and it remains the case that there is no scientific rationale for a different product from 6m-12m) that these are called '*Follow-up formula*' and that any milks marketed for children from 1-3y are called '*Fortified milks for young children*'. There is no rationale for the term formula to be used for these products.

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	Minimum	Maximum	GUL
Unit			
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			

<input checked="" type="checkbox"/> Codex Infant Formula standard 1.8 g /100 kcal 0.43 g /100 kJ	<input type="checkbox"/> 1.65 g /100 kcal 0.39 g /100 kJ	
<i>Please provide scientific justification and applicable references to support your response:</i>		
Infants in the first year of life require infant formula if they are not breastfed, and therefore follow on formula should align to the IF standard.		
Maximum		
<input type="checkbox"/> 3.5 g /100 kcal 0.84 g /100 kJ	<input checked="" type="checkbox"/> Codex IF std 3.0 g /100 kcal 0.72 g /100 kJ	<input type="checkbox"/> EFSA 2.5 g /100 kcal 0.60 g /100 kJ
<i>Please provide scientific justification and applicable references for your response:</i>		
Infants in the first year of life require infant formula if they are not breastfed, and therefore follow on formula should align to the IF standard		
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 or if you consider that further work is required.		
<input checked="" type="checkbox"/> insert Annex I (or refer) to the Codex Standard for Infant Formula	<input type="checkbox"/> review the levels contained within the Codex Standard for Infant Formula.	
<i>If you consider that a review is required, please indicate the basis for this review.</i>		
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.		
<input checked="" type="checkbox"/> All formulas based on hydrolysed protein should be clinically evaluated	<input type="checkbox"/> Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated	
<i>Please provide justification for your response.</i>		
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 .		
<input checked="" type="checkbox"/> intact milk protein	<input type="checkbox"/> non-hydrolysed milk protein	
<i>Please provide justification for your response.</i>		
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?		
<input type="checkbox"/> Yes, all formulas containing 1.65-1.8 g/100 kcal require clinical evaluation	<input type="checkbox"/> Yes, all formulas containing 1.65-2.0 g/100 kcal require clinical evaluation	<input type="checkbox"/> no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal
<i>Please provide justification for your response.</i>		
It might be useful to wait for the EFSA review of safety and acceptability of lower protein formula before		

agreeing these points.

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:

We believe this should be µg/100kcal/kJ not mg. We support these figures as any standard for FuF should align with those for the IF standard.

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:

Wherever possible the FUF standard should align with the IF standard.

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
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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 support these figures.

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 acid²¹⁾

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

FUF should align to IF standards wherever possible.

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.

<input type="checkbox"/> Two purposes: acidification of formula and supplementation with probiotics	<input checked="" type="checkbox"/> For the purpose of acidification of formula only . Contains minimal amounts of viable bacteria.	<input type="checkbox"/> For the purpose of supplementing with probiotics only
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Please provide justification for your preferred response:

There is an increasing body of evidence that suggest no efficacy for the addition of live microorganisms to infant milks, and the potential risks associated with unknown long-term consequences of this, and the way that milks must be reconstituted if probiotics are included are a concern for infant health.

A precautionary principle approach should be adopted here since infants are a highly vulnerable group and there is significant scientific uncertainty in this area.

If lactic acid cultures are used then there should aim to be a minimal residual amount of bacteria, but consistent recommendations in the labelling of all formula should be that they are reconstituted at a temperature to destroy any microorganisms present.

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.
<input type="checkbox"/> The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence <input type="checkbox"/> Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria <input checked="" type="checkbox"/> For the purpose of producing acidified formulas <input type="checkbox"/> Non-pathogenic lactic acid cultures may be used OR <input type="checkbox"/> No additional wording is required. Alignment with the Codex Infant Formula Standard
<i>Please provide justification for your response and any proposed draft text:</i>
As stated above and previously raised at the CCNFSDU, there is no consensus on benefit from the use of probiotic strains in infant formula, and unknown risk.

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

We would like the eWG to consider changing the name of these products to 'Fortified milks for older children' and to remove the term formula so that these products do not become confused with products marketed to families for use in the first year of life.

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 : <ul style="list-style-type: none"> 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.
<i>Answer:</i> In principle yes, but care needs to be taken that the compositional parameters of these products ensures that they do not inadvertently become inappropriate substitutes for breastmilk or other accepted milk alternatives for children specified in local public health guidance. This aspect particularly applies to the content of sugar and overall energy provision of these fortified milks, where currently there are a large number of high energy, high sugar products marketed as suitable in this age range that may contribute to childhood obesity and dental caries as well as the promotion of a 'sweet tooth' impacting on lifelong food choices.
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.
<i>Answer:</i> The addition of nutrients to fortified milks should not undermine or put at risk local public health initiatives to promote good nutrition in the early years, encourage dependence on highly processed products that are not in line with the WHO Global strategy on infant and young child feeding or potentially lead to high

intakes of nutrients where local supplementation may also be in place.

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:

It is important that voluntary additions of nutrients by manufacturers are controlled and therefore we support the general view that these should not exceed min and max in IF and FuF or conform to the legislation of the country in which the product is sold. The middle bullet point is too general and open to abuse since there is no clear definition of 'scientific justification' and we would prefer to see this point removed.

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. Milk should not be the main source of energy and nutrients in the diet of young children. If diets or appetites are poor and it is considered appropriate for a young child to continue on a fortified milk product beyond 1 year of age, then this can be IF – and we propose that as far as possible FuF aligns to IF composition, We do not agree with the principle stated here that appears in bullet point 2 above.

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:

We would propose that any voluntary additional nutrients added must conform to the legislation in the area in which the product is sold and that there are clear limits on the addition of substances, none of which should have allowable health claims to be made about them if they are not considered essential and therefore included in the 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:

Just because a substance is present in human milk does not mean the addition of a similar substance to a processed milk product has any efficacy, as known for example around the addition of nucleotides to IF and FuF. The addition of substances is frequently used to make health claims which are counter productive. The standard for fortified milks for young children should focus on minimizing any risk to health of unnecessary additions and in ensuring that in providing some useful nutrients it does not risk harm through unsuitable composition elsewhere.

QUESTION:

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

Answer:

Please provide justification for your answer:

Yes if there is clarity about control on voluntary additions and health claims.

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:

It is important the overall energy content of fortified milks for older children are controlled as the market is currently allowing a wide range of highly unsuitable products within the current Codex standards, and this may not be immediately obvious where information is given in absolute compositional terms. Because the current standard does not specify minimum and maximum carbohydrate contents, within the current min/max for protein and fat this allows for very high sugar intakes. Theoretically based on current Codex standards, if a fortified milk were to contain the minimum permissible levels of protein and fat, and the maximum permissible energy density, the nutritionally available carbohydrate content could reach 12.4g/100ml or 3.7g/100kJ. This is equivalent to 58% of energy in the product coming from free sugars. An average 1-3 year old having 5% of their energy intake from free sugars would require only 13.0g free sugar in the diet per day from all sources and this should be considered when considering how these fortified milk products may be formulated within proposed changes to fat and protein levels. Using both total intakes and intakes expressed as a percentage of energy may help member states in their work on sugar reduction policy and in ensuring consistency across WHO and national guidance.

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?

- | | |
|---|--|
| <input checked="" type="checkbox"/> FUF-older infants & full fat cows' milk
60 kcal/100ml
250 kJ/100 ml | <input type="checkbox"/> Reduced fat cows' milk (~1.5-2% fat)
45 kcal/100 ml
188 kJ/100 ml |
|---|--|

Please provide justification for your answer

The energy standard for fortified milks for young children should align with whole animal milk or IF/FUF standard. Children aged 1-2y still require relatively energy dense diets and whilst it could be argued that from 2-3y the reduced fat cows' milk standard is appropriate, the standard should aim to meet the needs of the most needy in the group as a principle. This raises serious questions as to how these products would fit into a healthy balanced diet following local nutrition guidance, and we urge modelling of diets in the second and third year of life to be done to consider the impact of these products on energy and nutrient intakes.

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:

Yes – the maximum energy content of fortified milks for young children should be specified so that there is a limit to the addition of carbohydrates possible and to ensure that if the min and max fat and protein levels are used that there is a natural ceiling to this. We would propose a maximum energy density of 70kcal/100ml for fortified milks for older children in line with IF/FUF and whole cows' milk. Modelling should be undertaken to show how different products would look within the standards agreed for fat and protein to ensure that carbohydrate and energy content ensure products do not undermine global attempts to reduce free sugars in the diets of children. Many products currently marketed sit within the energy range 60-70kcal/100ml – those with higher energy contributions we have reviewed are all high in sugar, but some of those within the 60-70kcal range also contribute significant amounts of sugar so the macronutrient and energy contents need to be carefully considered.

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

Yes. Minimum and maximum amounts are needed for all macronutrients and for energy to ensure that products meet the principles set for these fortified milks or benefit not hard. Modelling using different parameters would be useful to consider the scientific evidence in real world scenarios, and considering products currently marketed.

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

Alignment with the FUF standard should be considered.

Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
<input type="checkbox"/> Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	<input type="checkbox"/> Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
<input type="checkbox"/> Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	<input type="checkbox"/> Alternative value, please specify
<i>Please provide justification for your answer</i> <p style="color: red;">The macronutrient contents need to be considered as a piece – to ensure that the energy content and macronutrient content minimum and maximum values protect the market from unnecessary high sugar products. Modelling needs to be done to put these suggestions into a real world context.</p>	
Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?	
<input type="checkbox"/> Proposed FUF-older infants & cows' milk 6.0 g/100 kcal 1.4 g/100 kJ	<input type="checkbox"/> Alternative value, please specify
<i>Please provide justification for your answer</i> <p style="color: red;">A maximum value is needed as part of the modelling process already outlined.</p>	

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.	
<i>Please provide justification for your answers.</i> <p style="color: red;">If these products are marketed as a nutritional safety net for children post FuF then as far as possible they should include those nutrients that the eWG consider important in FUF for older infants (which we would prefer to call simply FuF).</p>	
Should a range for the ratio of linoleic: α -Linolenic acid be established for follow-up formula for young children?	
<input checked="" type="checkbox"/> 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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Alternative, please specify and provide justification for your answer.	<input type="checkbox"/> No

Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?	
<input checked="" type="checkbox"/> Yes Should this level be $\leq 20\%$ 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? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Alternative, please specify and provide justification for your answer.	<input type="checkbox"/> 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.	
<input type="checkbox"/> Yes Please state what the maximum level should be, and provide justification for your answer.	<input type="checkbox"/> No
Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (<i>Commercially hydrogenated oils and fats shall not be used in follow-up formula</i>) also apply to follow-up formula for young children?	
<i>Please provide justification for your answer.</i> Yes. Any provisions considered important for the protection of infant health should also be incorporated into any standard for children 1-3y.	

Carbohydrates

Please note in this section carbohydrate standards should be expressed as g/100kcal not mg/100kcal.

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?	
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Please provide your rationale:</i> In light of global work to reduce free sugars in the diets of all populations we need clarity over the carbohydrate content of all foods, giving both minimum and maximum figures which work within energy and other macronutrient criteria.	
If you support establishing a minimum available carbohydrates level, what level do you support?	
<input checked="" type="checkbox"/> Full fat cows' milk 7.5 g/100 kcal 1.8 g/100 kJ	<input type="checkbox"/> IEG 2015 and proposed Codex FUF-OI 9.0 g/100 kcal 2.2 g/100 kJ
<i>Please provide your rationale:</i> The basis of most fortified milks for young children will be 'milk and the level of carbohydrate in cows' milk	

should be the optimum amount requiring no additional carbohydrate. We suggest modelling takes place to consider how products currently marketed meet various criteria and the variation that might be plausible to meet other global health recommendations.

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:

For all the reasons previously described. Without a maximum value then fortified milks for older children will continue to provide significant amounts of unnecessary free sugars to the diets of young children. A maximum figure is essential.

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:

Modelling should be undertaken to expose current products which have very high carbohydrate contents within current regulations and to propose product compositions where fat, protein, carbohydrate and energy contents together do not undermine young child health.

If you support establishing a maximum/GUL, do you support 14 g/100 kcal (3.3 g/100 kJ)?

Yes No (please specify your alternative).

Please provide your rationale:

Before a maximum figure can be established there needs to be modelling which considers all of the scenario related to min and max values for energy and macronutrients. A lower figure closer to that of 9g/100kcal may be more appropriate and needs discussion.

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.

<input type="checkbox"/> 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.	<input checked="" type="checkbox"/> IEG 2015 Sugars other than lactose should be $\leq 10\%$ of total carbohydrates or 5% of total energy content	<input type="checkbox"/> An alternative level (please specify)
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Please provide your rationale:

As far as possible limits should reflect global public health recommendations to limit free sugars.

Lactose

<input type="checkbox"/> Proposed Codex FUF-OI Standard and Codex IF Standard	<input type="checkbox"/> IEG 2015
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Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.	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.	
<i>Please provide your rationale:</i>		
This needs further reflection when other figures have been established to model potential scenarios.		
Other permitted carbohydrates		
<input type="checkbox"/> Proposed Codex FUF-OI Standard	<input checked="" type="checkbox"/> IEG 2015	<input type="checkbox"/> Something else (please specify)
Only precooked and/or gelatinised starches gluten-free by nature may be added. (NB Glucose polymers are preferred carbohydrates along with lactose).	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.	
<i>Please provide your rationale:</i>		
This again requires further consideration when products can be reviewed against other agreed standards to see the real life implications of these additions.		

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?			
<input checked="" type="checkbox"/> Yes, a maximum level should be established		<input type="checkbox"/> No	
<input type="checkbox"/> Yes, a GUL level should be established			
<i>Please provide your rationale:</i>			
Whilst further scientific data is required to establish potential risk of excess iron consumption in early life on later outcomes, the precautionary principle should ensure that there is a maximum figure which aligns to the FuF standard.			
If you support establishing a maximum or GUL, please select your preferred value, providing scientific rationale to support your preferred choice.			
<input checked="" type="checkbox"/> Maximum (Proposed Codex FUF-OI) 2.0 mg/100 kcal 0.5 mg/100 kJ		<input type="checkbox"/> GUL (IEG 2015) 3.0 mg/100 kcal 0.7 mg/100 kJ	
<input type="checkbox"/> Alternative value (please provide level (max/GUL))			
<i>Please provide your rationale:</i>			
If intakes of fortified milks of 500ml per day are recognized as typical for children aged 1-3 years (and we might argue this is higher than needed) and fortified milks have an average energy of 65kcal/100ml, then this level provides iron in an amount that meets total UK iron requirements for 97.5% of all children 1-3			

years, providing a considerable safety margin for many.

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?

Yes No

Please provide your rationale:

Consideration must be given to absorption of iron.

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	[50] [90] [200]	[N.S.]	[180] [NS]
mg/100 kJ	[18] [22] [24] [48]		[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.

If as assumed in this paper the intake of fortified milks would be 500ml per day (please note there is an error on page 60 where it suggests that 500kcal of milk would be consumed – this would be 800ml) at standards of 50mg, 90mg and 200mg/100kcal, assuming energy content of 65kcal/100ml, this would provide 165mg/300mg/650mg/day. The UK RNI for calcium for 1-3y olds is 350mg/day and therefore we would support maintaining this as the FUF standard of 90mg/100kcal if the purpose of this fortified milk is to be a nutritional safety net for poor diets.

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	Max
1:1	2:1
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Please provide your rationale:</i>	

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			
<input checked="" type="checkbox"/> Current Codex FUF Std & proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	<input type="checkbox"/> IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	<input type="checkbox"/> WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ	
<i>Please provide your rationale:</i>			
75µg/100kcal will provide 375µg/day if 500ml milk consumed which if the aim is for this products to act as a nutritional safety net provides just under the UK DRV for vitamin A for 1-3 year olds. However, modelling should be done to consider whether if this amount of milk is consumed alongside national recommendations for children's vitamin supplementation that intakes are not likely to become excessive since all of the vitamin A will be retinol.			
Maximum			
<input type="checkbox"/> Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ		<input type="checkbox"/> Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ	
<i>Please provide your rationale:</i>			
Modelling is needed to consider potential intakes if these higher levels are consumed alongside local guidance on vitamin supplementation at this age.			
GUL			
<input type="checkbox"/> WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ		<input type="checkbox"/> IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ	
<i>Please provide your rationale:</i>			
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:

The addition should be in line with current recommendations on daily intakes based on average intakes of 500ml fortified milk per day.

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:

All nutrients require maximum levels but the decision on a maximum amount should be done alongside modelling from countries where there are other public health measures in place to ensure vitamin D sufficiency in the population.

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 align with the FuF standard

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:

Yes. This should align with the FuF standard.

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 align with the FuF standard

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:

Yes, this should align with the ustandard.

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:

Levels of all nutrients in fortified milks should be equivalent to or greater than whole cows' milk equivalent so that they are not a inferior choice for some nutrients which might be impacted by processing. Aligning with FuF standards provides consistency.

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:

All nutrients should have a maximum level in line with FuF standard.

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:

Levels of all nutrients in fortified milks should be equivalent to or greater than whole cows' milk equivalent so that they are not a inferior choice for some nutrients which might be impacted by processing. Aligning with FuF standards provides consistency

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:

All nutrients should have a maximum level in line with FuF standard.

Sodium

Sodium	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.	
<i>Answer:</i>	
Modelling should be done to ensure that sodium levels are within acceptable limits considering potential additions from diets in different areas.	
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.	
<i>Answer:</i>	
Yes – modelling is needed as above.	

SCOPE & LABELLING

<p>Scope & Labelling</p> <p>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.</p>
<p>Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?</p> <p><i>Please provide justification for your answer.</i></p> <p>1. Please consider renaming these products so that they are distinguishable – as described at the beginning we refer to FuF as the standard for 6-12m and fortified milks for young children as the standard for 12-36m.</p> <p>2. All labelling of all products must be in line with the WHO Code of marketing of breastmilk substitutes and subsequent WHA resolutions, including that from WHA69 which clearly states that all breastmilk substituted marketed from 1-3y are covered by the WHO Code and subsequent WHA resolutions. All products covered by this standard are breastmilk substitutes.</p>
<p>Are there any labelling areas where different provisions may be required for the two age groups?</p> <p><i>Please provide justification for your answer.</i></p> <p>All products should clearly state the age of child for which they are suitable and the superiority of breastfeeding as well as considering all the other labelling restrictions and safety measures highlighted by the Code and subsequent WHA resolutions. Marketing of fortified milks for young children currently cross-promotes infant formula and undermines breastfeeding and this has been clearly documented. It is essential that we use this opportunity to reflect WHO guidance and standards in this market to protect vulnerable families from inappropriate marketing through labelling.</p>
<p>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.</p> <p><i>Answer:</i></p> <p>We hope that this will reflect all the current global thinking and work within the WHO and that there will be clear coordination between Codex and WHO in setting these important standards.</p>
<p>Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up</p>

Formula, and if so, how and where? For example in the Scope and Labelling sections.

Answer:

Yes – this needs careful consideration and discussion.

Please comment on how CCFSDU 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:

As far as possible Codex should review the FuF standards in their entirety to ensure they are in line with the WHA resolution, whilst considering that some additional work is needed to model product composition, look at products currently marketed and to provide better evidence on how these products can potentially protect, rather than harm infant health. Recommendation 3 in the WHA resolution guidance document clearly states that '*Relevant Codex standards and guidelines should be updated and additional guidelines developed in line with WHO's guidance to ensure that products are appropriate for infants and young children*'. We hope that all eWG members recognize this as a significant opportunity to protect infant and young child health and that the WHO resolution is not dealt with in a tokenistic fashion within a 'business as usual' model.

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:

Yes – clearly this must now be deleted as any milk product marketed for children from 0-3 years are now defined as breastmilk substitutes as per the WHA69 resolution and guidance. We again urge consideration of the naming of these products to ensure there is no confusion between products marketed and safe for use from 0-12 months and those products marketed for 1-3 years. All are covered by the Code and resolutions but it is very important there is no confusion about suitability.