

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: **IBFAN**

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

CODEX CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD CAC/RCP 20-1979 4.4: National authorities should be aware of their obligations under the International Health Regulations (2005) with regard to food safety events, including notification, reporting or verification of events to the World Health Organisation (WHO). They should also make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed.

IBFAN would first like draw the EWG attention to the need for policy coherence between WHO and Codex and the urgent need to ensure that this standard is in full conformity with all WHO policies, in particular with WHA Resolutions 63.23 and 69/9 and the Guidance on ending the inappropriate marketing of foods for infants and young children. (A69/7 Add 1)

We reiterate that standard infant formula can be used to the age of 12 months and beyond when mothers decide not to breastfeed. IBFAN is concerned that the marketing of age-targeted processed milks can be confusing and misleading and very often leads to inappropriate and needless use. The term follow-up formulas, although in wide use, is misleading as are the many descriptions of processed milks for older infants and young children that can be de-facto health claims. (Growing up milk, Toddler Milks etc)

The risks of the needless use and prolonged bottle feeding of these products are well documented, especially in relation to NCDs and the undermining of breastfeeding..

IBFAN strongly recommends that the category of milks for older infants be eliminated since IF can be used when necessary to the age of 12 months and beyond. Products targeted for use from 12 to 36 months should use the term “processed milks for young children”.

In 2013 and 2014 EFSA published opinions on the essential composition of IF and FOF and Young Child Formula (YCF).^{1 2}. After an extensive literature review EFSA recommended minimal compositional difference between IF and FOF (apart from a slight difference in target iron levels). EFSA also found no scientific evidence, or insufficient evidence, to support the inclusion of many of the ingredients commonly used in formulas and promoted as having a health benefit. EFSA went further to warn that the unnecessary addition of nutrients can be a burden to a young child. FOF (apart from a slight dif “From a nutritional point of view, the minimum contents of nutrients in infant and follow-on formula proposed by the Panel cover the nutritional needs of virtually all healthy infants born at term and there is no need to exceed these amounts in formulae, as nutrients which are not used or stored have to be excreted and this may put a burden on the infant’s metabolism. Therefore, the Panel emphasises that maximum amounts should be interpreted not as target values but rather as upper limits of a range which should not be exceeded.”³

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			
x Codex Infant Formula standard		☒	
1.8 g /100 kcal		1.65 g /100 kcal	
0.43 g /100 kJ		0.39 g /100 kJ	
<i>Please provide scientific justification and applicable references to support your response:</i>			
When infants are not breastfed, infant formula can be used during the first 12 months of life. As stated many times by WHO and public health bodies “Follow on formula” is not necessary. If products are to be placed on the market targeting children over 6 months (IBFAN believes they should not) then their composition should be aligned as far as possible to IF.			
Maximum			
☒	☒	☒	
3.5 g /100 kcal	Codex IF std 3.0 g /100 kcal	EFSA 2.5 g /100 kcal	

¹ Scientific Opinion on the essential composition of infant and follow-on formulae 2014 www.efsa.europa.eu/en/efsajournal/pub/3760.htm

² ‘Growing-up’ formula: No additional value to a balanced diet, says EFSA, 25th October 2013 <http://www.efsa.europa.eu/en/press/news/131025>

³ Scientific Opinion on the essential composition of infant and follow-on formulae, EFSA, EFSA Journal 2014;12(7):3760

0.84 g /100 kJ	0.72 g /100 kJ	0.60 g /100 kJ
<p>Please provide scientific justification and applicable references for your response:</p> <p>When infants are not breastfed, infant formula can be used during the first 12 months of life. As stated many times by WHO and public health bodies “Follow on formula” is not necessary. If products are to be placed on the market targeting children over 6 months (IBFAN believes they should not) then their composition should be aligned as far as possible to IF.</p>		
<p>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.</p>		
<input 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.	
<p>If you consider that a review is required, please indicate the basis for this review.</p>		
<p>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</p>		
<p>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.</p>		
<input 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	
<p>Please provide justification for your response.</p> <p>All formulas based on hydrolysed protein should be clinically evaluated by independent evaluators. Quality of the evidence: Any decisions regarding this Standard and its need should be evidence-based rather than ‘consensus-based.’ All evidence should meet WHO’s definition of scientific substantiation: ‘Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification.’ If products are to be placed on the market targeting children over 6 months (IBFAN believes they should not) then their composition should be aligned as far as possible to IF.</p>		
<p>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.</p> <p>Please state whether you support the proposal to amend the reference these types of formulas to intact milk protein.</p>		
<input type="checkbox"/> intact milk protein	<input type="checkbox"/> non-hydrolysed milk protein	
<p>Please provide justification for your response.</p>		
<p>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?</p>		
<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
<p>Please provide justification for your response.</p>		

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

<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
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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:

If products are to be placed on the market targeting children over 6 months (IBFAN believes they should not) then their composition should be aligned as far as possible to IF.

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

<input type="checkbox"/> Codex IF Standard 10 mg/100 kcal 2.5 mg/100 kJ Taking a precautionary approach and aligned with the Codex Infant Formula Standard	<input type="checkbox"/> 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.
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Please provide your preferred response:

If products are to be placed on the market targeting children over 6 months (IBFAN believes they should not) then their composition should be aligned as far as possible to IF.

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:

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.			
<input checked="" type="checkbox"/> Yes		<input checked="" type="checkbox"/> No	
<p>When infants are not breastfed, infant formula can be used during the first 12 months of life. If products are to be placed on the market for children over 6 months (IBFAN believes they should not) then their composition should be aligned as far as possible to IF.</p> <p>Optional ingredients are used for marketing purposes and come with additional risks, such as more additives and contaminants in the product as well as unintended risks. It is essential that the Precautionary Principle is used and that “optional” ingredients are added only when they have been found to be “essential”.</p> <p>The Quality of the evidence used to determine this must meet WHO’s definition of scientific substantiation: ‘Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification.’</p> <p>DHA: Given the lack of post-market surveillance and the weakness and inconsistency of the available evidence - especially in relation to its efficacy for older babies – steps must be taken to limit any risk of the addition of DHA.</p>			

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 type="checkbox"/> For the purpose of acidification of formula only . Contains minimal amounts of viable	<input type="checkbox"/> For the purpose of supplementing with probiotics only

	bacteria.	
<i>Please provide justification for your preferred response:</i>		
<p>A number of meta analysis have determined that there is insufficient evidence for the claims made for the addition of live microorganisms to infant milks. However there is evidence of potential health risks associated with unknown long-term consequences of microbial additions. There can be serious health consequences when the products are in powdered form and are reconstituted at temperatures to preserve the added <i>Lactobacilli</i>, below temperatures recommended for safe preparation. This increases the risk of infection from Cronobacter and Salmonella organisms.</p> <p>Such risks are particularly significant for formula fed infants, who are a highly vulnerable group for infection due to their immuno-compromised status.</p>		
<p>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).</p>		
<p>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.</p>		
<p><input type="checkbox"/> The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence</p> <p><input type="checkbox"/> Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria</p> <p><input type="checkbox"/> For the purpose of producing acidified formulas</p> <p><input type="checkbox"/> Non-pathogenic lactic acid cultures may be used</p> <p>OR</p> <p><input type="checkbox"/> No additional wording is required. Alignment with the Codex Infant Formula Standard</p>		
<p><i>Please provide justification for your response and any proposed draft text:</i> Same as above</p>		

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

IBFAN recommends changing the name of these products to ‘Processed milks for young children’ and to remove the term formula so that these products do not become confused with Infant Formula. The term “formula” can imply feeding by bottle which can undermine breastfeeding, increase dental caries and problems of malocclusion and exacerbate the risk of childhood obesity.

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:

If the term “milk” is used in the definition and product name then the composition must meet the requirements for use of the word “milk”.

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:

The modification of nutrients in processed milks should not undermine or put at risk adherence to global or national or public health policies. Any commercial promotion that encourages excessive intake of nutrients and dependence on highly processed products contradicts the intent of WHA Resolutions 63.23 and 69/9 and the Guidance on ending the inappropriate marketing of foods for infants and young children. (A69/7 Add 1) and the WHO Global Strategy on Infant and Young Child Feeding.

After an extensive literature review EFSA recommended minimal compositional difference between IF and FOF (apart from a slight difference in target iron levels). EFSA also found no scientific evidence, or insufficient evidence, to support the inclusion of many of the ingredients commonly used in formulas and promoted as having a health benefit. EFSA went further to warn that the unnecessary addition of nutrients can be a burden to a young child’s metabolism: (our emphasis)

“From a nutritional point of view, the minimum contents of nutrients in infant and follow-on formula proposed by the Panel cover the nutritional needs of virtually all healthy infants born at term and there is no need to exceed these amounts in formulae, as nutrients which are not used or stored have to be excreted and this may put a burden on the infant’s metabolism. Therefore, the Panel emphasises that maximum amounts should be interpreted not as target values but rather as upper limits of a range which should not be exceeded.”⁴

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.

⁴ Scientific Opinion on the essential composition of infant and follow-on formulae, EFSA, EFSA Journal 2014;12(7):3760

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.

IBFAN does not support “voluntary nutrient additions”.
It should again be noted that these modified milks are not necessary nutritionally and that normal mammalian milk such as cow’s milk is a much cheaper and safer source of nutrients and can easily fit into the complementary feeding diet for older infants and young children.

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:

IBFAN does NOT agree. Since human milk is a substantial source of energy and nutrients in the diet of young children, we propose that processed milks must align as closely as possible to IF composition. We do not agree with the principle stated here that is a reiteration of 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:

IBFAN is of the opinion that the composition of these processed milks must be aligned either to infant formula or to unsweetened, unflavoured milk. If there is to be a standard for these products then it must meet WHO’s definition of scientific substantiation: ‘Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification.’
The scientific basis for the efficacy and safety of voluntary ingredients is weak at best and all too often relies of governments requesting scientific substantiation of efficacy from manufacturers. This is a totally inadequate approach for such a vulnerable target population. Instead the Standard should require that:

- a) all ingredients used in products for this should be pre-authorized following rigorous independent scrutiny, (with particular care over new technologies, such as nanotechnologies;
- b) systematic reviews of all available evidence should be carried out *independently* of the manufacturers and distributors of the products in question;
- c) evidence should be reviewed on a regular basis to ensure infants are not exposed to levels of nutrients that might put a burden on their metabolism, (a concern already raised by EFSA);⁵
- d) regular post market surveillance should occur indicating the frequency of such reviews;
- e) food ingredients not listed as essential should be kept to the bare minimum;

The addition of optional ingredients creates opportunities for idealising promotional including health and nutrition

UK Government's Scientific Advisory Committee on Nutrition (SACN) stated that the notion of optional/voluntary ingredients is unethical: "... If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods."¹¹

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:

See above. IBFAN does not agree with the addition of "optional ingredients".

QUESTION:

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

Answer:

Please provide justification for your answer:

See above. IBFAN does not agree with the addition of "optional ingredients".

Energy contribution from macronutrients

Energy contribution from macronutrients

Please provide comment and justification as to whether it is necessary to define specific macronutrient

⁵ *ibid*

percentage contribution to overall energy.

Answer:

The overall energy content of products targeting children over 12 months must be controlled. The products currently on the market include a wide range of highly unsuitable products with very high sugar intakes – These products may well fall within the permitted range of the current standard (that does not specify minimum and maximum carbohydrate contents). This could allow 58% of energy in the product to come from free sugars.

Any Codex Standard or Guidance must help Member states establish policies that will achieve policy coherence with WHO norms on sugar, salt, etc.

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 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

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?	
<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>	
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>	

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>	
Should a range for the ratio of linoleic: α -Linolenic acid be established for follow-up formula for young children?	
<input 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 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 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	<input type="checkbox"/> No

reduced fat cows' milk? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Alternative, please specify and provide justification for your answer.	
Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
<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>	

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?	
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Please provide your rationale:</i>	
If you support establishing a minimum available carbohydrates level, what level do you support?	
<input checked="" type="checkbox"/> Full fat cows' milk 7.5 mg/100 kcal 1.8 mg/100 kJ	<input checked="" type="checkbox"/> IEG 2015 and proposed Codex FUF-OI 9.0 mg/100 kcal 2.2 mg/100 kJ
<i>Please provide your rationale:</i>	
If limits are established for sugars, is there a need to also set a maximum/GUL for total available carbohydrates?	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<i>Please provide your rationale:</i> Yes. It is essential that a maximum figure is specified. Without a maximum value then fortified milks for young children will continue to provide significant amounts of unnecessary free sugars to the diets of young children. If these products are to be placed on the market they should not be sweetened (with free or intense sugars) or flavoured.	
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?	
<input checked="" type="checkbox"/> Yes, a maximum level should be established	<input checked="" type="checkbox"/> Yes, a GUL level should be established
<i>Please provide your rationale:</i>	
If you support establishing a maximum/GUL, do you support 14 mg/100 kcal (3.3 mg/100 kJ)?	

<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No (please specify your alternative).
<p><i>Please provide your rationale:</i></p> <p>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.</p> <p>WHO recommends a reduction in intake of free sugars throughout the lifecycle. In both adults and children, WHO recommends that intake of free sugars should not exceed 10% of total energy intake (strong recommendation). WHO also suggests that a further reduction of the intake of free sugars to below 5% of total energy intake would have additional health benefits.</p>	

Carbohydrates footnote		
<p><i>Free sugars</i></p> <p>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.</p>		
<input checked="" 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 ≤ 10% of total carbohydrates or 5% of total energy content	<input type="checkbox"/> An alternative level (please specify)
<p><i>Please provide your rationale:</i></p> <p>Sugar and fructose should not be added to these products. Limits should be in line with WHO global public health recommendations to limit free sugars.</p> <p>WHO has expressed concern regarding the potential negative health effects of commercially available foods for infants and young children < 2 years of age notably through:</p> <ul style="list-style-type: none"> • The undermining of exclusive breastfeeding for the first six months of life and the replacement of, rather than complementing, intake of breast milk in children beyond six months • An increased risk of childhood obesity or risk factors relating to cardiovascular diseases, diabetes and cancer due to excess intake of energy, free sugars, salt and/or fat • The reinforcement of sweet or salty taste preferences leading to the development of undesirable and unhealthy preferences and dietary habits in early childhood. 		

Lactose		
<input type="checkbox"/> Proposed Codex FUF-OI Standard and Codex IF Standard	<input type="checkbox"/> IEG 2015	
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>		
Other permitted carbohydrates		
<input type="checkbox"/> Proposed Codex FUF-OI Standard	<input 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>		

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 type="checkbox"/> Yes, a maximum level should be established <input type="checkbox"/> Yes, a GUL level should be established		<input type="checkbox"/> No	
<i>Please provide your rationale:</i>			
It is important to have a maximum figure to avoid the documented negative health consequences of excessive iron.			
If you support establishing a maximum or GUL, please select your preferred value, providing scientific rationale to support your preferred choice.			
<input 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>			
Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?			

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<i>Please provide your rationale:</i>	
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)?	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No (please provide alternative values, with justification for your response)
<i>Please provide your rationale:</i>	

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:			
<input type="checkbox"/> Current Codex FUF standard 90 mg/100 kcal 22 mg/100 kJ		<input type="checkbox"/> Proposed Codex FUF standard for older infants 50 mg/100 kcal 12 mg/100 kJ	
<input type="checkbox"/> IEG 2015 200 mg/100 kcal		<input type="checkbox"/> Alternative value, please specify	
<i>Please provide justification for your answers.</i>			
Maximum/GUL:			
<input type="checkbox"/> Current Codex FUF standard Maximum: N.S.		<input type="checkbox"/> Proposed Codex FUF standard for older infants GUL: 180 mg/100 kcal GUL: 43 mg/ 100 kJ	
<input type="checkbox"/> IEG 2015 GUL: N.S.		<input type="checkbox"/> 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 checked="" 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 checked="" type="checkbox"/> IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	<input checked="" type="checkbox"/> WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ
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Please provide your rationale:

Maximum

<input checked="" type="checkbox"/> Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	<input checked="" type="checkbox"/> Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ
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Please provide your rationale:

GUL

<input checked="" type="checkbox"/> WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ	<input checked="" type="checkbox"/> IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ
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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?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
<i>Answer:</i>	
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.	
<i>Answer:</i>	

Vitamin C

Vitamin C	
Do you support that mandatory addition of vitamin C to follow-up formula for young children?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
<i>Answer:</i>	
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.	
<i>Answer:</i>	

Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
<i>Answer:</i>	
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.	
<i>Answer:</i>	

Riboflavin

Riboflavin	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
<input type="checkbox"/> Yes	<input type="checkbox"/> 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?	
<input 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.	
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?
<i>Please provide justification for your answer. The name of the food should be clear and not confuse parents and care givers and should minimize the health risks associated with misuse and needless use. IBFAN recommends that a more informative name is: processed milks for young children.</i>
Are there any labelling areas where different provisions may be required for the two age groups?
<i>Please provide justification for your answer.</i> Powdered processed milks for young children should be labeled
<ul style="list-style-type: none"> - that they are not sterile and the labels should be in accordance with the FAO/WHO. 2007. Safe preparation, storage and handling of powdered infant formula: guidelines. - That they should not be used before the age of 12 months. - With a clear statement that these products are not necessary and that human milk and or other mammalian milks such as cow's milk are appropriate milks for young children as part of the complementary feeding diet.

Parents are unaware of the global consensus that fortified milks for young children are not only *not necessary*^{6 7} but can also pose a risk to health. The marketing masks the fact that these products:

- **Have higher sugar content: “Fortified milks are frequently high in sugar and are likely to contribute to higher energy intakes, which may contribute to chronic disease, and the voluntary fortification of foods and drinks needs to be questioned as there is increasing evidence that giving additional nutrients to those who do not need them may have adverse consequences.”**⁸
- **They are expensive.**^{9.10}
 - **They are often cross-branded with IF so risk undermining of breastfeeding.**¹¹

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:

The Scope, Labelling and marketing provisions of this standard should conform to the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant WHA resolutions. 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.

WHA69.9: “ Reaffirming the need to promote exclusive breastfeeding practices in the first 6 months of life, and the continuation of breastfeeding up to 2 years and beyond, and recognizing the need to promote optimal complementary feeding practices for children from ages 6–36 months based on WHO² and FAO dietary guidelines and in accordance with national dietary guidelines;”

⁶ WHA Resolution (WHA 39.28) adopted in 1986 3. REQUESTS the Director-General 3(2) to specifically direct the attention of Member States and other interested parties to the following:...(b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.

⁷ 'Growing-up' formula: No additional value to a balanced diet, says EFSA, 25th October 2013
<http://www.efsa.europa.eu/en/press/news/131025>

⁸ First Steps Nutrition Trust: http://www.firststepsnutrition.org/pdfs/Statement%20on%20Growing-up%20milks_July_2014.pdf

^{9a}.... recommended daily serving of powdered toddler milk can cost up to £235 per year, using ready-to-feed toddler milk increases this cost to up to £593, the annual cost of 300ml of cow's milk is £62..... Cow's milk contains 4.7g sugar per 100ml, compared to 7.9g of sugar per 100ml of Hipp Organic Combiotic Growing up milk. And some daily servings contain twice as much sugar - three teaspoons a day for cow's milk compared to seven teaspoons a day for SMA Toddler milk.

SMA Toddler milk also contains vanilla flavouring, which encourages children to prefer sweetened products.

<http://www.which.co.uk/news/2013/08/should-parents-buy-toddler-milks-330947/>

¹⁰ A survey by the German consumer centres on the products being sold as “Kindermilch” (“milk for children”) targeting the age from 12 months found that Kindermilch was up to four times more expensive than normal milk, costing parents up to 245 euros more each year.

<http://www.vzhh.de/ernaehrung/129727/kostenfalle-kindermilch.aspx>

¹¹ Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy, Cattaneo A, et al. Arch Dis Child 2014;0:1–6

Guidance:

A69/7 Add.1

11. Recommendation 2. 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.

WHA 63.23 2010: 1(4) urged Member States to: “end inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation”

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 this is essential. The scope of the standard should require full compliance with the International Code of Marketing of Breastmilk Substitutes WHA 32.22(1981) and all relevant WHA resolutions on infant and young child nutrition, especially WHA 39.28; 47.5; WHA 49.15; WHA 54.2; WHA55.25; WHA 58.32; WHA61.20; WHA63.23; WHA69.9.

Please comment on how CCNFSDU should ‘give full consideration’ to Resolution (A69/A/CONF.17 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:

**(OP2)(1), (2), (3), (4)
(OP3)**

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

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

Answer:

This is very important. As mentioned above WHA69.9 and A69/7 Add 1 clarify WHO’s long held position that products marketed for children under 36

months are breastmilk substitutes. The statement must be deleted.

Guidance:A69/7 Add 1 11. Recommendation 2. Products that function as breastmilk substitutes should not be promoted. A breastmilk 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.

One of the consistent findings of review exercises looking at the effects of marketing is that it operates at the brand level, in addition to product and category level. Much marketing is carried out with the aim of building brand awareness/recognition and brand loyalty (Cairns et al, 2013; Hastings et al, 2006). In sum, when marketing follow-- on formula, companies may also effectively promote breast milk substitutes. Techniques used to build the brand---consumer relationship include the use of brand marketing alone (e.g. use of common logos and messages, which may cut across products and product categories). It has been shown that brand preference often precedes purchase or purchase requests, and that brand marketing has the ability to influence purchase and preference for products not necessarily featured in the marketing. This may result in its early introduction, thereby undermining exclusive breastfeeding up to six months of age and sustained breastfeeding up to two years or beyond.