

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
ENCA
July 2015

Please respond by **10th July 2015**
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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".

DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)

STRUCTURE	
Two approaches were proposed by eWG members for the structure of section 2. Description, please indicate your preferred approach:	
Should the structure of section 2. Description be;	
<p><input checked="" type="checkbox"/> Aligned with the Codex IF std</p> <p>2. DESCRIPTION 2.1 Product Definition 2.1.1 Follow-up Formula means a food intended... 2.1.2 Follow-up Formula is a food processed by physical means... 2.2 Other Definition 2.2.1 The term <i>infant</i> means... 2.2.2 The term <i>young child</i> means...</p> <p>Move current FUF definitions to other sections: <i>2.2 moved to 3.1 Essential composition</i> 2.2 Follow-up formula is a food prepared from the milk... <i>2.4 mover to 9.5.1 Information for Use</i> 2.4 Follow-up formula when in liquid form, is suitable for use....</p>	<p><input type="checkbox"/> Modified</p> <p>2. DESCRIPTION 2.1 Product Definition 2.1.1 Follow-up Formula means a food intended... 2.1.2 The term <i>infant</i> means... 2.1.3 The term <i>young child</i> means... 2.2 Product Description 2.2.1 Follow-up formula is a food prepared from the milk... 2.2.2 Follow-up Formula is a food processed by physical means... 2.2.3 Follow-up formula when in liquid form, is suitable for use....</p>
Please provide comment and justification for your answers if you support a different approach.	
There is no rationale for a different composition for milks marketed for infants 6-12 months than for those 0- 6 months, and therefore as part of a longer term move to provide one standard for all milks for infants 0-12 months, alignment with the current IF standard wherever possible makes sense.	

DEFINITION 2.1.1

Current Codex Standard for Follow-up Formula text:

Follow-up formula means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

Please comment on whether you support a broad definition for follow-up formula, or one definition which incorporates separate product categories. See the following examples;

a) Follow-up formula means a food intended for use as

OR

b) Follow-up formula means a food used by:

- [older] infants from 6 months (followed by role and purpose in the diet)..... and,
- young children (followed by role and purpose in the diet).

We would prefer the wording to read:

'Follow-up formula is a breastmilk substitute which can be used as a liquid part of the progressively diversified diet for older infants and young children.'

The Chairs propose that *'from the 6th month'* be replaced with *'from 6 months'* within the definition for follow-up formula. If you do not support this approach, please provide comment and justification for your answers.

Thank you – we are pleased to see this change.

The Chairs propose that the term 'weaning diet' is not used in the definition of follow-up formula. If required, it should be replaced with 'complementary feeding'. If you do not support this approach, please provide comment and justification for your answers

We agree that the term 'weaning' should not be used and if required the term complementary feeding should be used.

The Chairs propose inclusion of the terminology ***progressively diversified diet*** in the definition for follow-up formula. If you do not support this approach, please provide comment and justification for your answers

We agree with the inclusion of this wording.

DEFINITION 2.1.2 & 2.1.3

2.1.2 The term ***infant*** means a person of not more than 12 months of age

2.1.3 The term ***young child*** means persons from the age of more than 12 months up to the age of three years (36 months)

Based on eWG responses and to retain consistency with other relevant Codex texts, the Chairs propose retaining the current definition 2.1.2 and 2.1.3 in their current drafting. Please provide comment and justification for your answers if you do not support this approach.

We agree

OLDER INFANT

The Chairs propose *either* including a definition for 'older infant' (as defined in the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013) in the Follow-up Formula Standard, OR including a reference to/qualifier of 'older infant' within the definition 2.1.1 of follow-up formula. Please select your preferred approach.

As the group have agreed that standards will differ for infants 6-12m to those for children 12-36m a definition related to all the age groups referred to will be needed.

DEFINITION 2.1.4

Current Codex Standard for Follow-up Formula text:

The term calorie means a kilocalorie (kcal). 1 kilojoule (kJ) is equivalent to 0.239 calories (kcal)

Based on eWG responses, the Chairs propose deleting definition 2.1.4 related to the term calorie. Please provide comment and justification if you do not support this approach

We have no objection to this definition staying in place.

DEFINITION 2.2

Current Codex Standard for Follow-up Formula text:

Follow-up formula is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

Based on eWG responses to align terminology, the Chairs propose the following draft text as a starting point. The Chairs propose including a comma after the wording 'other animals' so that it is clear that it is the other ingredients that need to have been to be suitable (not the milk base).

***Follow-up formula** is a ~~food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,~~ [product based on milk of cows or other animals or a mixture thereof,] and/or other ingredients] which have been proved to be suitable [and nutritionally adequate] for [the intended age range]. ~~infants from the 6th month on and for young children.~~*

Please provide comment on the above suggested wording as well as; should any additional wording from the equivalent statement from the Infant Formula Standard be incorporated into the definition for follow-up formula, should the concept of 'safety' be captured in the definition, should all ingredients/additives in follow-up formula be gluten free, and should the statement include wording around 'supporting growth and development'?

We would prefer the text to read:

2.2.1 Follow-up formula is a breastmilk substitute made from ingredients which have been independently proved to be safe and suitable and which support appropriate growth and development of older infants and young children.

DEFINITION 2.3

Current Codex Standard for Follow-up Formula text:

Follow-up formula is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

Based on eWG responses to align terminology, the Chairs propose amending this definition to align with the equivalent statement within point 2.1.1 of the Infant Formula Standard.

[Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold]-

Please provide comment on the above suggested wording.

We support the alignment of this text with the Infant Formula Standard.

DEFINITION 2.4

Current Codex Standard for Follow-up Formula text:

Follow-up formula, when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use

The Chairs propose that the information contained within definition 2.4 of the Follow-up Formula Standard be moved to Section 9.5 with consideration of the appropriate wording to be given at the time that that section 9.5 is reviewed. If you do not support this approach, please provide comment and justification for your answers.

We agree.

ESSENTIAL COMPOSITION

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

We have highlighted our options in yellow

Macronutrients

Protein			
No consensus was reached on the establishment of protein requirements. Please provide scientific rationale to support your preferred value:			
Protein Unit	Minimum	Maximum	GUL
g/100 kcal	[1.8] [1.7] [1.65]	[3.0] [2.5] [3.5]	-
g/100 kJ	[0.45][0.41][0.39]	[0.7] [0.6] [0.8]	-
Minimum			
<input type="checkbox"/> Codex IF std 1.8 g/ 100 kcal 0.45 g/ 100 kJ	<input type="checkbox"/> 1.7 g/100 kcal 0.41 g/100 kJ	<input type="checkbox"/> 1.65 g/100 kcal 0.39 g/100 kJ	
If supporting a value other than the Codex IF std please provide supporting scientific evidence			
We also support the inclusion of different minimum values for soy protein in line with those provided by EFSA (2014)			
If supporting a value other than the Codex IF std please provide comment on how the energy, total fat, and carbohydrate content requirements should be amended to accommodate this.			
Maximum			
<input type="checkbox"/> Codex IF std 3.0 g/ 100 kcal 0.7 g/ 100 kJ	<input type="checkbox"/> EFSA/IEG 2.5 g/100 kcal 0.6 g/100 kJ	<input type="checkbox"/> 3.5 g/100 kcal 0.8 g/100 kJ	
Please provide rationale:			
We also support the inclusion of different maximum values for soy protein and protein hydrolysates in line with those provided by EFSA (2014)			
If supporting a value other than the Codex IF std please provide comment on how the energy, total fat, and carbohydrate content requirements should be amended to accommodate this.			

Protein Footnote 2

²For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

Or

²For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25 **[or as specified in a relevant Codex commodity Standard or the Codex Recommended Methods of Analysis and Sampling]** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.

Retain as footnote 2 in the Codex IF std

Amend to reflect the use of other Codex texts

Please provide rationale:

Footnote 3

Taking into account comments from the eWG, do you support the removal of the sentence related to ratios of amino acids?

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. ~~[The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing.]~~

Yes

No

Do you support the inclusion of Annex I as the reference protein for the compositional requirements for follow-up formula for older infants?

Yes

Footnote 4

⁴ Isolated amino acids may be added to _____ value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

Do you support the inclusion of footnote 4 as amended slightly by the Chairs?

Yes

Footnote 5

The following wording is proposed to improve the clarity of the footnote:

⁵ The minimum value applies to cows' [_____
formula based on non-cows' milk protein other minimum values may need to be applied.
For infant formula based on soy protein isolate, a minimum value of [2.25 g/100 kcal (0.5
g/100 kJ)] applies.

Do you support the modified footnote? Noting that the minimum value may change dependent on the outcome of the minimum protein content of formulas based on cows' milk protein.

We support this – wording needs to say follow up formula not infant formula.

Can there be an additional sentence that says 'minimum values for follow up formula made from other protein hydrolysates should be established based on independent clinical evaluation.

Footnote 6

⁶ Infant [Formula based on non-hydrolysed milk protein containing less than [2 g protein/ 100 kcal] and] infant [formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].

Do you support the inclusion of the amended footnote 6? If no, please provide rationale for the modifications proposed.

We suggest:

Follow up formula based on non-hydrolysed milk protein containing less than 1.8g protein/ 100 kcal, follow up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal and any follow up formula based on other protein hydrolysates should be independently clinically evaluated for safety and suitability.

Total Fat

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support the the Total fat minimum and maximum values?

Total fat Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.05	1.4	-

Yes

No, if no please provide scientific justification

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support alignment of the Total fat footnotes regarding lauric and myristic acid, and erucic acid?

- Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids.
- The erucic acid content shall not exceed 1% of total fatty acids.

Yes No, if no please provide scientific justification

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support alignment of the Total fat footnotes regarding use of commercially hydrogenated fats, and trans fat?

- Commercially hydrogenated oils and fats shall not be used in **infant follow-up** formula
- The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in **infant follow-up** formulae.

Yes No, if no please provide scientific justification

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support alignment of the Total fat footnotes regarding phospholipids?

- The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Yes No, if no please provide scientific justification

Linoleic and α-linolenic acid

No eWG consensus was reached on the minimum and GUL requirements for LA. Please provide scientific rationale to support your preferred value:

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	[300] [500]	-	[1400] [1200]
mg/100 kJ	[70] [120]	-	[330] [300]

Codex IF std
300 mg/100 kcal
70 mg/100 kJ

EFSA
500 mg/100 kcal
120 mg/100 kJ

Please provide your rationale:

No eWG consensus was reached on the establishment of a ratio of LA:ALA in line with the Codex Standard for Infant Formula, or the establishment of a maximum requirement for ALA.

Please provide scientific rationale to support your preferred approach:

Codex IF std
Ratio linoleic/α-linolenic acid
Min 5:1
Max 15:1

EFSA
ALA max:
100 mg/100 kcal
24 mg/100 kJ

Please provide your rationale:

Docosahexanoic acid & Arachidonic acid

Several eWG members considered that DHA and ARA compositional requirements should be included in the Standard. Do you consider that these fatty acids should be considered optional ingredients, as per the Codex Infant Formula Standard, or mandated? Please provide scientific rationale to support your preferred approach.

Codex IF std
Optional addition

Mandated

Please provide your rationale:

These should remain optional as there is no evidence for their efficacy in improving the health and well-being of older infants. However we do not wish to see claims being made for any optional ingredients on follow up formula and hope that this can be considered when labelling aspects are debated.

If you support inclusion of DHA compositional requirements to the Codex Standard for follow-up formula for older infants (either as an optional or essential addition), do you support the inclusion of provisions for ARA and EPA? Please provide scientific rationale to support your preferred approach.

Total Carbohydrates

The majority of the eWG members support the option to align the total carbohydrate requirements of the Codex Infant and Follow-up Formula standards. However this may need to be amended if the protein requirements between the two standards differ.

Total Carbohydrates	Minimum	Maximum	GUL
Unit	9.0	14.0	-
g/100 kcal	2.2	3.3	-
g/100 kJ			

If consensus is reached to amend the Energy, Protein and Total Fat minimum and maximum levels to those established in the Codex Standard for Infant Formula, do you support alignment of the two standards regarding the minimum and maximum carbohydrate content?

Yes

No

Please provide your rationale:

If the Codex Standard for Infant Formula minimum and maximum values for Energy, Protein, or Total Fat are not adopted, do you support reviewing the minimum and maximum carbohydrates based on the residual energy content?

Yes

No

Please provide your rationale:

Carbohydrate Footnote

In addition to stating that lactose should be **a** preferred carbohydrate, should a minimum lactose content of 4.5g/100 kcal be specified, unless a product is "lactose free" or more than 50% of the protein is from soy protein isolate?

Yes, support minimum lactose level

No do not support minimum lactose level

Lactose should be **the** preferred carbohydrate in follow up formula, as this is a breastmilk substitute and lactose is the predominant carbohydrate in breastmilk.

Should glucose polymers be specified as the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein? Or should the addition of glucose be limited only to formula made from protein hydrolysates?

Glucose polymers considered preferred carbohydrate in formula based on cows' milk protein and hydrolysed protein

Addition of glucose limited to formula made from protein hydrolysates

The eWG support that the addition of precooked and/or gelatinized starches that are gluten-free nature may be added to follow-up formula.

Do you support that a limit to the percentage of total carbohydrates should be established?

addition up to 30% total carbohydrates

unrestricted addition within maximum total carbohydrate limits

We agree with the assessment by EFSA. We would like to see this extended to:

Starches should not be added in concentrations higher than 2 g/100 ml (2.9-3.3 g/100 kcal (0.7-0.8 g/100 kJ)) and that they should not constitute more than 30 % of total carbohydrates.

Some eWG members recommended that a maximum limit should be established for the addition of sucrose and fructose.

Do you support the inclusion of a maximum limit for the addition of sucrose and fructose, and if so that the sum of sucrose and fructose should not exceed 20% of total carbohydrates?

Yes

No

We support the EFSA conclusion that The maximum concentration should be $\leq 20\%$ of total carbohydrates for sucrose and ≤ 2 g/100 kcal (≤ 0.5 g/100 kJ) for glucose.

If your response to the above question was yes, do you think that the sum of sucrose and fructose should also include sugar from honey if treated to destroy spores of *C. botulinum*?

Yes

No

It is problematic to include honey as an ingredient in any food for infants under 12 months of age as this is likely to be out of line with any national guidance, and therefore confusing to caregivers. The inclusion of honey treated to destroy spores of *C. Botulinum* should be restricted to products marketed for infants over 12 months of age and no claims should be allowed for the use of this as an alternative carbohydrate source.

Fat-soluble Vitamins

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

Unit	Minimum	Maximum	GUL
µg RE/100 kcal	[75] [70] [60]	[225] [180] [140] [114]	-
µg RE/100 kJ	[18] [16.7] [14]	[54] [43] [33.4] [27.2]	-

¹⁰⁾ 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 type="checkbox"/> Codex FUF std 75 µg RE/100 kcal 18 µg RE/100 kJ	<input type="checkbox"/> EFSA 70 µg RE/100 kcal 16.7 µg RE /100 kJ	<input type="checkbox"/> Codex IF std 60 µg RE/100 kcal 14 µg RE/100 kJ
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Please provide your rationale:

In general we would prefer there to be as much consistency between the Codex IF and FuF standard as possible as these products are both breastmilk substitutes. The EFSA review based their recommendation on equivalence with breastmilk in the first 6 months of life, but as FuF are given alongside an increasingly diversified diet then a slightly lower value as in Codex IF standard is acceptable.

Maximum

<input type="checkbox"/> Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	<input checked="" type="checkbox"/> Codex IF std 180 µg RE/100 kcal 43 µg RE/100 kJ	<input type="checkbox"/> 140 µg RE/100 kcal 33.4 µg RE/100 kJ	<input type="checkbox"/> 114 µg RE /100 kcal 27.2 µg RE/100 kJ
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Please provide your rationale:

Vitamin D

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

Vitamin D

Unit	Minimum	Maximum	GUL
µg/100 kcal	[1] [2]	[2.5] [3.0] [4.5]	-
µg/100 kJ	[0.25] [0.48]	[0.6] [0.75] [1.1]	-

11) Calciferol. 1 µg calciferol = 40 IU vitamin D

Minimum

- | | |
|--|--|
| <input type="checkbox"/> Codex IF std
1 µg /100 kcal
0.25 µg /100 kJ | <input type="checkbox"/> EFSA
2 µg /100 kcal
0.48 µg /100 kJ |
|--|--|

Please provide your rationale:

Maximum

- | | | |
|---|---|--|
| <input type="checkbox"/> Codex IF std
2.5 µg /100 kcal
0.6 µg /100 kJ | <input type="checkbox"/> Codex FUF std
3.0 µg /100 kcal
0.75 µg /100 kJ | <input type="checkbox"/> IEG
4.5 µg /100 kcal
1.1 µg /100 kJ |
|---|---|--|

Please provide your rationale:

This is complicated since there may be a number of other initiatives in place to ensure adequacy of Vitamin D among infants in many countries and a rationale based on IF may not be the most appropriate. We think this needs further discussion, but would support in general the use of the Codex IF standard for consistency.

Vitamin E

No consensus was reached on the establishment of a minimum vitamin E value. Please provide scientific rationale to support your preferred value:

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE /100 kcal	[0.5] [0.6]	-	5
mg α-TE /100 kJ	[0.12] [0.14]	-	1.2

Minimum

- | | |
|---|--|
| <input type="checkbox"/> Codex IF std
0.5 mg α-TE /100 kcal
0.12 mg α-TE /100 kJ | <input type="checkbox"/> EFSA
0.6 mg α-TE /100 kcal
0.14 mg α-TE /100 kJ |
|---|--|

Please provide your rationale:

Vitamin K

No consensus was reached on the establishment of a minimum vitamin K value. Please provide scientific rationale to support your preferred value:

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 kcal	[4] [1]	-	27
µg/100 kJ	[1] [0.24]	-	6.5

Minimum

Codex IF std
4 µg /100 kcal
1 µg /100 kJ

EFSA
1 µg /100 kcal
0.24 µg /100 kJ

Please provide your rationale:

Water Soluble Vitamins

Thiamin			
No consensus was reached on the establishment of a minimum thiamin value. Please provide scientific rationale to support your preferred value:			
Thiamin Unit	Minimum	Maximum	GUL
µg/100 kcal	[60] [40]	-	300
µg/100 kJ	[14] [10]	-	72
<i>Minimum</i>			
<input type="checkbox"/> Codex IF std 60 µg /100 kcal 14 µg /100 kJ	<input type="checkbox"/> Codex FUF std/ EFSA 40 µg /100 kcal 10 µg /100 kJ		
<i>Please provide your rationale:</i>			
Where possible the standards for IF and FuF should be aligned within Codex standards.			

Riboflavin			
No eWG consensus was reached on the establishment of a minimum riboflavin value. Please provide scientific rationale to support your preferred value:			
Riboflavin Unit	Minimum	Maximum	GUL
µg/100 kcal	[80] [60]	-	500
µg/100 kJ	[19] [14]	-	119
<i>Minimum</i>			
<input type="checkbox"/> Codex IF std 80 µg /100 kcal 19 µg /100 kJ	<input type="checkbox"/> EFSA 60 µg /100 kcal 14 µg /100 kJ		
<i>Please provide your rationale:</i>			

Niacin			
No eWG consensus was reached on the establishment of a minimum niacin value. Please provide scientific rationale to support your preferred value in square brackets:			
Niacin* Unit	Minimum	Maximum	GUL
µg/100 kcal	[300] [400]	-	1500
µg/100 kJ	[70] [100]	-	360
* Niacin refers to preformed niacin			
<i>Minimum</i>			

<input type="checkbox"/> Codex IF std 300 µg /100 kcal 70 µg /100 kJ	<input type="checkbox"/> Codex FUF std/ EFSA 400 µg /100 kcal 100 µg /100 kJ
<i>Please provide your rationale:</i>	

Vitamin B6

No eWG consensus was reached on the establishment of a minimum Vitamin B6 value. Please provide scientific rationale to support your preferred value in square brackets:

Vitamin B6*

Unit	Minimum	Maximum	GUL
µg/100 kcal	[35] [20]	-	175
µg/100 kJ	[8.5] [4.8]	-	45

*[*Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein.]*

Minimum

<input type="checkbox"/> Codex IF std 35 µg /100 kcal 8.5 µg /100 kJ	<input type="checkbox"/> Codex FUF std/ EFSA 20 µg /100 kcal 4.8 µg /100 kJ
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Please provide your rationale:

Inclusion of the footnote:

Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein

Yes No

Please provide your rationale:

Folic acid

No eWG consensus was reached on the establishment of a minimum folic acid/folate value. Please provide scientific rationale to support your preferred value in square brackets:

Folic acid Unit	Minimum	Maximum	GUL
µg/100 kcal	[10]	-	[50]
µg/100 kJ	[2.5]	-	[12]

OR

Folate*

Folate* Unit	Minimum	Maximum	GUL
µg/100 kcal	[15]	-	[85]
µg/100 kJ	[3.6]	-	[20]

*[*expressed as dietary folate equivalents (DFE)
1 µg DFE = 1 µg food folate = 0.6 µg folic acid]*

Should composition be based on folate or folic acid?

<input type="checkbox"/> Folic acid	<input type="checkbox"/> Folate, expressed as dietary folate equivalents
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Please provide your rationale:
 The absorption efficiency of folates varies depending on their chemical form and for clarity dietary folate equivalents should be given.

If you support establishing compositional requirements for folate, do you support the inclusion of a footnote defining dietary folate equivalents as presented in square brackets above?

Please provide your rationale:
 Yes

Vitamin C

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

Vitamin C 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	<input type="checkbox"/> EFSA 4 mg/100 kcal 0.96 mg/100 kJ
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Please provide your rationale:
 For consistency we support the alignment of the IF and FuF standards.

Do you support the inclusion of footnote 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

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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Please provide your rationale:
 Could this be reworded to say:
 The GUL of 70mg/100 kcal applies only to ready to feed liquid products which may experience high losses over shelf-life; powdered products should not exceed the upper level of 17mg/100kcal.

Biotin

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

Biotin	Minimum	Maximum	GUL
Unit µg/100 kcal	[1.5] [1]	-	10
µg/100 kJ	[2.5] [0.24]	-	2.4
Minimum levels			
<input type="checkbox"/> Codex IF Standard 1.5 µg/100 kcal 2.5 µg/100 kJ	<input type="checkbox"/> EFSA 1 µg/100 kcal 0.24 µg/100 kJ		
<i>Please provide your rationale:</i>			

Minerals & Trace Elements

Iron			
No consensus was reached on the compositional requirements for iron for Follow-up Formula composition. Based on the eWG responses, please provide scientific rationale to support your preferred value in square brackets			
Iron	Minimum	Maximum	GUL
Unit mg/100 kcal	[0.45] [0.6] [1.0] [1.1]	[2.0] [1.9] [1.5] [2.5]	-
mg/100 kJ	[0.1] [0.14][0.25] [0.26]	[0.3] [0.45] [0.36] 0.6]	-
Minimum			
<input type="checkbox"/> Codex IF 0.45 mg/100 kcal 0.1 mg/100 kJ	<input type="checkbox"/> EFSA 0.6 mg/100 kcal 0.14 mg/100 kJ	<input type="checkbox"/> Codex FUF 1 mg/100 kcal 0.25 mg/100 kJ	<input type="checkbox"/> IEG 1. mg/100 kcal 0.26 mg/100 kJ
<i>Please provide your rationale:</i>			
We would like to see consistency between the IF and FuF standards wherever possible. We have concerns about the potential impact of high doses of iron on children and as FuF is a breastmilk substitute given alongside a progressively fortified diet, composition should reflect that of breastmilk.			
Should maximum levels be established?			
<input type="checkbox"/> Yes	<input type="checkbox"/> No, a footnote should be added stating: “levels may be determined by National Authorities”		
<i>Please provide your rationale:</i>			
Whilst there may not be conclusive evidence about the impact of high iron intakes on longer health and development a body of evidence suggests that the precautionary principle should be used.			
If you support establishing a maximum level please provide scientific rationale to support your preferred value in square brackets			

<input type="checkbox"/> Codex FUF 2.0 mg/100 kcal 0.5 mg/100 kJ	<input type="checkbox"/> IEG 1.9 mg/100 kcal 0.45 mg/100 kJ	<input type="checkbox"/> 1.5 mg/100 kcal 0.36 mg/100 kJ	<input type="checkbox"/> 2.5mg/100 kcal 0.6 mg/100 kJ
<i>Please provide your rationale:</i>			
New proposed EU regulations suggest a maximum value of 1.3mg/100kcal for IF and we would support that.			
Should separate minimum and maximum/GUL levels be established for soy protein isolate formulas?			
<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<i>Please provide your rationale:</i>			

Calcium & phosphorous			
No consensus was reached on the requirements for calcium for Follow-up Formula composition.			
Calcium	Minimum	Maximum	GUL
Unit			
mg/100 kcal	[50] [90]	-	[140] [180]
mg/100 kJ	[12] [22]	-	[35] [43]
Minimum			
<input type="checkbox"/> Codex IF std 50 mg/100 kcal 12 mg/100 kJ	<input type="checkbox"/> Codex FUF std 90 mg/100 kcal 22 mg/100 kJ		
<i>Please provide your rationale:</i>			
Guiding upper level			
<input type="checkbox"/> Codex IF std 140 mg/100 kcal 35 mg/100 kJ	<input type="checkbox"/> Codex FUF std 180 mg/100 kcal 43 mg/100 kJ		
<i>Please provide your rationale:</i>			
No consensus was reached on the requirements for phosphorous for Follow-up Formula composition.			
Phosphorous	Minimum	Maximum	GUL
Unit			
mg/100 kcal	[25] [60]	-	[100] [120] [N.S.]
mg/100 kJ	[6] [14]	-	[24] [29] [N.S.]
Minimum			
<input type="checkbox"/> Codex IF std 25 mg/100 kcal 6 mg/100 kJ	<input type="checkbox"/> Codex FUF 60 mg/100 kcal 14 mg/100 kJ		

Please provide your rationale:

Guiding upper level
Do you consider that calcium and phosphorous ratios are taken into account when establishing a GUL? For example if the maximum calcium content is increased, should the phosphorous content also be extended?

Yes No

Please provide your rationale:

Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula be included?
Ratio calcium/phosphorous

Min	Max
1:1	2:1

Yes No

Please provide your rationale:

Should a footnote be attached to the GUL for phosphorous indicating its applicability to formula containing soy protein isolate?
¹⁸⁾ This GUL should accommodate higher needs with soy formula

Yes No

Please provide your rationale:

Sodium, chloride & potassium

No consensus was reached on the minimum or maximum requirements for sodium for Follow-up Formula composition.

Sodium Unit	Minimum	Maximum	GUL
mg/100 kcal	[20] [25]	[60] [85]	-
mg/100 kJ	[5] [6]	[14] [21]	-

Minimum

Codex IF std
20 mg/100 kcal
5 mg/100 kJ

EFSA
25 mg/100 kcal
6 mg/100 kJ

Please provide your rationale:

Maximum

Codex IF std
60 mg/100 kcal
14 mg/100 kJ

Codex FUF std
85 mg/100 kcal
21 mg/100 kJ

Calculated based on max protein compositional requirement

Please provide your rationale:

No consensus was reached on the minimum requirements for chloride for Follow-up Formula composition.

Chloride

Unit	Minimum	Maximum	GUL
mg/100 kcal	[50] [60]	[160]	-
mg/100 kJ	[12] [14.3]	[38]	-

<input type="checkbox"/> Codex IF std 50 mg/100 kcal 12 mg/100 kJ	<input type="checkbox"/> EFSA 60 mg/100 kcal 14.3 mg/100 kJ
--	---

Please provide your rationale:

No consensus was reached on the minimum requirements for chloride for Follow-up Formula composition.

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[60] [80]	[180]	-
mg/100 kJ	[14] [19.1]	[43]	-

<input type="checkbox"/> Codex IF std 60 mg/100 kcal 14 mg/100 kJ	<input type="checkbox"/> EFSA 80 mg/100 kcal 19.1 mg/100 kJ
--	---

Please provide your rationale:

If you propose to adapt the maximum sodium, chloride and potassium composition on the maximum protein composition, please specify how this would be achieved.

Manganese

No consensus was reached on the minimum requirements for manganese for Follow-up Formula composition.

Manganese

Unit	Minimum	Maximum	GUL
µg/100 kcal	[1] [N.S.]	-	[100]
µg/100 kJ	[0.25] [N.S.]	-	[24]

Do you support the establishment of a minimum requirement for manganese?

<input type="checkbox"/> 1 µg /100 kcal 0.25 µg /100 kJ	<input type="checkbox"/> N.S.
---	-------------------------------

Please provide your rationale:

Do you support the establishment of a GUL for manganese of 100 µg/100 kcal

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	------------------------------------

Please provide your rationale:

A range of 1-100ug is excessive and out of line with most other ranges of minimum to maximum levels set. There is some evidence of risk associated with manganese in infant formula albeit this remains limited, but taking a precautionary principle approach, a value of 50ug/100kcal max could be suggested (http://jn.nutrition.org/content/119/12_Suppl/1861.full.pdf).

Iodine

No consensus was reached on the iodine requirements for Follow-up Formula composition. Please provide scientific rationale to support your preferred value:

Iodine

Unit	Minimum	Maximum	GUL
µg/100 kcal	[10] [15]	[29] [50] [60]	[29] [50] [60]
µg/100 kJ	[2.5] [3.6]	[7] [12] [14]	[7] [12] [14]

Minimum

- | | |
|---|--|
| <input type="checkbox"/> Codex IF std
10 µg /100 kcal
2.5 µg /100 kJ | <input type="checkbox"/> EFSA
15 µg /100 kcal
3.6 µg /100 kJ |
|---|--|

Please provide your rationale:

Upper limit

Should a Maximum or Guiding Upper Level be established?
At what level should this be set?

- | | | |
|---|---|---|
| <input type="checkbox"/> Maximum | <input type="checkbox"/> GUL | |
| <input type="checkbox"/> 60 µg /100 kcal
14 µg /100 kJ | <input type="checkbox"/> 50 µg /100 kcal
12 µg /100 kJ | <input type="checkbox"/> 29 µg /100 kcal
7 µg /100 kJ |

Please provide your rationale:

This is the maximum level in EU regulations for IF.

Selenium

No consensus was reached on the selenium minimum requirements for Follow-up Formula composition. Please provide scientific rationale to support your preferred value:

Selenium

Unit	Minimum	Maximum	GUL
µg/100 kcal	[1] [3]	-	9
µg/100 kJ	[0.24] [0.72]	-	2.2

Minimum

- | | |
|---|--|
| <input type="checkbox"/> Codex IF std
1 µg /100 kcal
0.24 µg /100 kJ | <input type="checkbox"/> EFSA
3 µg /100 kcal
0.72 µg /100 kJ |
|---|--|

Please provide your rationale:

Copper

No consensus was reached on the copper requirements for Follow-up Formula composition.
Taking into account the scientific rationale of the establishment Please provide your

Copper

Unit	Minimum	Maximum	GUL
µg/100 kcal	[35] [60]	-	[120] [250]
µg/100 kJ	[8.5] [14.3]	-	[29] [60]

Minimum

- | | |
|--|---|
| <input type="checkbox"/> 35 µg /100 kcal
8.5 µg /100 kJ | <input type="checkbox"/> 60 µg /100 kcal
14.3 µg /100 kJ |
|--|---|

Please provide your rationale:

New recommendation proposed by EFSA

Upper limit

- | | |
|---|---|
| <input type="checkbox"/> GUL
120 µg /100 kcal
29 µg /100 kJ | <input type="checkbox"/> GUL
250 µg /100 kcal
60 µg /100 kJ |
|---|---|

Please provide your rationale:

We would prefer the maximum value to be 100ug/100kcal as per current EU regulations for IF.

Inclusion of the footnote:

Adjustment may be needed in these levels for ~~infant~~ formula made in regions with a high content of copper in the water supply

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|------------------------------|-----------------------------|

Wording should say follow up formula.

This needs further discussion with examples of what maximum levels in some regions might be.

Zinc

The eWG consistently supports establishing a minimum zinc content of 0.5 mg/100 kcal. In establishing an upper limit for zinc,

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	[1.25] [1.5]	[1.25] [1.5]
mg/100 kJ	0.12	[0.3] [0.36]	[0.3] [0.36]

Should a <u>maximum</u> or <u>GUL</u> be established?	
<input type="checkbox"/> Max	<input type="checkbox"/> GUL
Should the upper limit be set at <u>1.5 mg/100 kcal</u> or <u>1.25 mg/100 kcal</u> ?	
<input type="checkbox"/> 1.5 mg/100 kcal 0.36 mg/100 kJ	<input type="checkbox"/> 1.25 mg/100 kcal 0.3 mg/100 kJ
Please provide your rationale: We support a maximum of 1mg/100kcal as per current EU regulations for IF.	
Should separate minimum and maximum/GUL levels be established for soy protein isolate formulas?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Please provide your rationale: FOF containing soy protein should have a minimum content of 0.75 mg/100 kcal (0.18 mg/100 kJ) and maximum of 1.25mg/100kcal as proposed by EFSA and in EU regulations for IF.	

Other substances

Choline, myo-inositol, L-carnitine			
No consensus was reached on the addition of choline to Follow-up Formula.			
Choline Unit	Minimum	Maximum	GUL
mg/100 kcal	[7] [-]	-	[50] [150]
mg/100 kJ	[1.7] [-]	-	[12] [36]
Should the addition be:			
<input type="checkbox"/> Mandatory Min: 7 mg/100 kcal 1.7 mg/100 kJ	<input type="checkbox"/> Not specified in the std	<input type="checkbox"/> Optional with GULs Min: - -	
Please provide your rationale: There is no rationale to add choline to FuF, but if we want as much consistency between IF and FuF as possible as they are all breastmilk substitutes, then mandatory addition makes the most sense.			
If you support either mandatory addition or the optional addition with a specified GUL, what GUL do you support?			
<input type="checkbox"/> Codex IF std GUL: 50 mg/100 kcal 12 mg/100 kJ		<input type="checkbox"/> IEG 2013 GUL: 150 mg/100 kcal 36 mg/100 kJ	

Please provide your rationale:

No consensus was reached on the addition of myo-inositol to Follow-up Formula.

Myo-inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	[4] [-]	-	[40] [-]
mg/100 kJ	[1] [-]	-	[9.5] [-]

<input type="checkbox"/> Mandatory Min: 4 mg/100 kcal 1 mg/100 kJ GUL: 40 mg/100 kJ 9.5 mg/kJ	<input type="checkbox"/> Not Specified in the std	<input type="checkbox"/> Optional with GULs Min: - - GUL: 40 mg/100 kJ 9.5 mg/kJ
--	---	--

Please provide your rationale:

There is no rationale to add inositol to FuF, but as above, in order to be as consistent as possible for all breastmilk substitutes we support mandatory addition.

No consensus was reached on the addition of L-carnitine to Follow-up Formula.

L-Carnitine

Unit	Minimum	Maximum	GUL
mg/100 kcal	[1.2] [-]	-	-
mg/100 kJ	[0.3] [-]	-	-

<input type="checkbox"/> Mandatory Min: 1.2 mg/100 kcal 0.3 mg/100 kJ	<input type="checkbox"/> Not Specified in the std	<input type="checkbox"/> Specified in section 3.2 Optional ingredients
--	---	---

Please provide your rationale:

As above we support mandatory addition for consistency between all breastmilk substitutes.

Optional ingredients

Do you support incorporating the provisions within 3.2.3 & 3.2.4 of the Infant Formula Standard into the Follow-up Formula Standard for product for older infants?

If yes, should the same minimum, maximum and GULs be aligned with the Infant Formula Standard for product for older infants, or should these be reviewed?

We would like to see consistency for composition of all breastmilk substitutes.

Based on eWG responses the Chairs propose the following for your consideration. Please comment on the following for the addition of optional ingredients to follow-up formula for older infants and provide justification and rationale for your responses:

Taking into account eWG responses to include the reference not only to vitamins and minerals, but other ingredients; and to take into consideration wording drafted in Section 2 Description.

3.3.2.1 In addition to the **[compositional requirements]** ~~vitamins and minerals~~ listed under 3.2.4 to 3.2.6, other ~~nutrients~~ **[ingredients]** may be added when required to ensure that the product is suitable to form part of [a mixed feeding scheme] OR **[progressively diversified diet]** OR **[complementary diet]** intended for use from the 6th months on.

Please comment on all wording in square brackets

What other ingredients might fall into this category? We are concerned that this would allow the addition of substances such as vegetable or fruit extracts that manufacturers will then use to make claims that products are able to provide older infants and young children with 'all their food groups' (as is currently the case), or that this will allow a range of additional claims relating to dietary adequacy. This needs further discussion with some idea of what types of ingredients may be added.

Taking into account eWG responses to align with the principles contained within the Codex Infant Formula standard 3.2.2, and that concept that the ingredient does not necessarily need to be present in breast milk, the following wording is proposed in square brackets:

3.2.2.2 [The suitability for the particular nutritional uses of [older] infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, ~~taking into account levels in human milk.~~]

Please comment on all wording in square brackets

We are concerned about this sentence. We would prefer it to say:

The suitability and safety of any additional ingredient added shall be scientifically demonstrated and evidence presented to an appropriate national or regional regulatory authority.

PROCESS TO REVIEW THE ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS)

Flexibility

Several eWG members stated that flexibility in the composition of products for young children was important due to the increased contribution of complementary foods to the diversified diet of young children.

Do you support an approach where not all nutrients or substances that have compositional requirements established for older infants are mandated for addition to follow-up formula for young children?

Yes

No

Please provide justification for your answer:

Follow up formula are breastmilk substitutes.

Do you support an approach that can encompass the views of the majority of the eWG in that the compositional requirements established for older infants can be used as a basis for the composition of product for young children, in addition to ensuring that milk based drinks can be considered within the compositional requirements for this age group? Please provide your comments.

Yes

No

Please provide justification for your answer:

Compositional requirements for young child drinks should be considered separately to the FuF standard. If the IF standard was extended to all products marketed for infants 0-12 months then there could be different considerations, but whilst this group remains within the standard then the emphasis must be on protecting the most vulnerable and ensuring any product marketed is considered a breastmilk substitute.

Are there other elements of flexibility that should be considered in the development of compositional requirements for follow-up formula for young children?

Please provide justification for your answer:

Key nutrients

Several eWG members referred to the findings of the 2014 eWG report on key nutrients for which there is evidence of inadequate intakes/status in the target population. Globally, iron and the quality of dietary fat were consistently found to be inadequate in sub-groups of the target population.

Do you consider that minimum compositional requirements for iron and fat quality will be required for product targeted to young children?

Please provide justification for your answer:

This needs further discussion.

Several eWG members referred to the findings of the 2014 eWG report and stated that the requirements should be flexible enough to provide a source of the nutrients identified to be lacking in several countries internationally: α -linolenic acid (ALA), docosahexanoic acid (DHA), vitamin A and D, calcium, zinc and iodine.

Do you consider that minimum compositional requirements for these nutrients should be required to ensure the nutritional integrity of product targeted to young children?

Please provide justification for your answer:

These are covered by compositional standards under discussion.

Do you consider that maximum compositional requirements for these nutrients should be required to ensure the nutritional integrity of product targeted to young children?

Please provide justification for your answer:

As above

Nutritional integrity

At a global level, what compositional parameters are considered important to mandate to ensure the nutritional integrity of product for the young child age group? (Consideration could be given to macronutrient and/or micronutrient requirements)

Please provide justification for your answer:

Am unclear how this question differs from considerations of composition above?

Do you consider that nutritional equivalence to products that follow-up formula may replace is required? If so, please specify, what nutrients should be equivalent, and comment whether their addition should be mandatory or voluntary?

Please provide justification for your answer:

FuF should be considered as breastmilk substitutes and therefore where appropriate equivalence to the IF standards, which are mandatory, should be a priority.

The eWG highlighted that consideration of the safety and suitability of nutrients and other substances, added to follow-up formula for young children is necessary and several proposed that the essential composition of follow-up formula for older infants should be used as a starting point.

If a nutrient or other substance is added to follow-up formula (whether mandatory or voluntary), what are your views on the minimum and maximum levels of addition being consistent with the levels in follow-up formula for older infants?

Please provide justification for your answer:

Whilst one standard exists for all FuF products then the needs of the youngest and most vulnerable within the age group should always be the priority.