

# 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 **19<sup>th</sup> 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: **Morocco**

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

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

#### Protein

Protein			
No agreement was reached on the establishment of a minimum or maximum protein value. Please provide scientific rationale to support your preferred value:			
Protein Unit	Minimum	Maximum	GUL
g/100 kcal	[1.8] or [1.65]	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39]	[0.84] or [0.72] or [0.60]	-
Minimum			
<input checked="" type="checkbox"/>	Codex Infant Formula standard 1.8 g /100 kcal 0.43 g /100 kJ	<input type="checkbox"/>	1.65 g /100 kcal 0.39 g /100 kJ
<i>Please provide scientific justification and applicable references to support your response:</i>			
<b>Milk is a good source of protein from animal food for old infant, identifying a minimum level is a good point, but currently, we need more scientific evidence to go below this limit.</b>			
Maximum			
<input type="checkbox"/>	3.5 g /100 kcal 0.84 g /100 kJ	<input checked="" type="checkbox"/>	Codex IF std 3.0 g /100 kcal 0.72 g /100 kJ
<input type="checkbox"/>		<input type="checkbox"/>	EFSA 2.5 g /100 kcal 0.60 g /100 kJ

*Please provide scientific justification and applicable references for your response:*  
**Obesity for under 5 years children is a problem in developed and developing countries, with many sociocultural and environmental factors, and the introduction of appropriate complementary food to fight against it, is still challenging in many countries. Thus, current scientific evidences tend to lower proteins intake, but at this level of scientific evidences, we are suggesting less dramatic decrease.**

**Footnote 3**

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

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

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

- |   |   |
|---|---|
| <input type="checkbox"/> insert Annex I (or refer) to the Codex Standard for Infant Formula | <input checked="" type="checkbox"/> review the levels contained within the Codex Standard for Infant Formula. |
|---|---|

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

**In term of essential and semi-essential aa, infant and old infant don't have the same need**

**Footnote 6**

The majority of the eWG supported retaining elements of footnote 6.

[<sup>6)</sup>Follow-up formula based on ~~non-hydrolysed~~ **intact** milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated

Regarding formulas based on **hydrolysed** protein, please state whether you think that all, or only those containing less than [2.25 g/100 kcal] should be clinically evaluated.

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> All formulas based on hydrolysed protein should be clinically evaluated | <input type="checkbox"/> Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated |
|---|---|

*Please provide justification for your response.*

**Formula based on hydrolysed protein is given for some specific medical indications, always, the formula is evaluated (whatever is its' protein level) to support the medical indication and the safe use, but there is no need to evaluate all formulas twice, if the formula exist in 2 presentations for infant and old infant and has been evaluated for infant, we don't need other evaluation for old infant (Normally it is not the case for these products, which always exist in one option suitable for both ages, but, it is the case only for some and rare partially hydrolysed formula, which are not included in this proposal)**

Regarding formulas based on **intact/non-hydrolysed** protein please note that your responses to these questions do not imply that you support a minimum of 1.8 g/100 kcal or 1.65 g/100 kcal. They will be used to refine the wording in square brackets if the eWG cannot come to agreement on a minimum value.

Please state whether you support the proposal to amend the reference these types of

**formulas to intact milk protein.**

<input checked="" type="checkbox"/> intact milk protein	<input type="checkbox"/> non-hydrolysed milk protein	
<p><i>Please provide justification for your response.</i>  <b>Because hydrolysed protein refers to industrial process in for specific medical situation, and the denomination should refer to the normal situation which is having intact protein in milk.</b></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 clinically evaluation	<input type="checkbox"/> Yes, all formulas containing 1.65-2.0 g/100 kcal require clinically evaluation	<input checked="" type="checkbox"/> no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal
<p><i>Please provide justification for your response.</i>  <b>Considering the fact that these products are for old infants, who are having complementary food, and considering that we have to give safe amount of food to normal population, we shouldn't have to evaluate the under 1.65 g/100 Kcal protein of all formula (if we choose this marge) , otherwise we are suggesting giving products at nutritional risk, no suitable to the nutritional need to these population.</b></p>		
<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 <b>Error! Reference source not found.</b>above</p>		
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	

**Vitamin K**

<b>Vitamin K</b>			
<p>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:</p>			
<b>Vitamin K</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 kcal	4	-	27
mg/100 kJ	1	-	6.5
<p><b><i>We confirm our agreement</i></b>  <b>The key steps to ensure adequate vitamin k status of children is to give vitamin K at birth, and to optimize dietary intake throughout early life. Because there is no sensitive Indicators for estimating the requirements for vitamin K, and lack of information on the bioavailability of dietary vitamin K in this age group, decreasing vitamin k could put infants at risk of bleeding, this risk increases in case of antibiotic treatment, diarrhea, malabsorption or under nutrition...In many countries, the oral Vit K supplementation</b></p>			

during the first 3 months is not a part of the national programme for the breastfed children and it is not stressed by these programme (as it is the case for vit A or D), it is always more a recommendation of pediatricians and scientific nutrition committees.

## 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<sup>15)</sup>

Unit	Minimum	Maximum	GUL
mg/100 kcal	[10] [4]	-	70 <sup>16)</sup>
mg/100 kJ	[2.5] [0.96]	-	17 <sup>16)</sup>

<sup>15)</sup> expressed as ascorbic acid

<sup>16)</sup> This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

#### Minimum levels

Codex IF Standard

10 mg/100 kcal

2.5 mg/100 kJ

Taking a precautionary approach and aligned with the Codex Infant Formula Standard

EFSA

4 mg/100 kcal

0.96 kJ/100 kcal

*Please provide your preferred response:* **There is no evidence for vitamin C deficiency when it is considered through the scurvy data. Thus, the minimum level could be reduced as proposed by EFSA. But tacking into account the balance between the impact of the decreasing of the Vit C during the shelf life, on the prevalence of inadequate intake among older infants and young children in different countries, Morocco suggest the alignment with Codex IF standard.**

## Zinc

### Zinc

Based on the views of the eWG and evidence provided, the Chairs propose the following drafting of zinc requirements for follow-up formula for older infants is recommended for adoption by the Committee

#### Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	-	1.5
mg/100 kJ	0.12	-	0.36

<sup>20)</sup> For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

*Agree with this proposal*

**Agree with the chair's proposal which are in line with the scientific evidence and we could avoid the technical constraints by maintaining the GUL at 1.5.**

**As EFSA recommended a minimum zinc value for formula based on soy protein isolate that was 1.5 times that of milk protein based formula, we keep a minimum value of 0.75 mg/100 Kcal.**

**Optional Ingredients: DHA**

<b>Docosahexaenoic acid (DHA)</b>			
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.			
<b>Docosahexaenoic acid<sup>21)</sup></b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
<b>Unit</b>	[ - ] or [ 0.3 ]	-	0.5
% fatty acids			
<sup>21)</sup> 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 type="checkbox"/> No	
<b>As it is an optional ingredient, we agree with this compromise, giving the minimum level of 0.3% as indication and the GUL, and the flexibility to the National authority as suggested.</b>			

**Optional Ingredients: L(+) lactic acid producing cultures**

<b>Optional addition L(+) lactic acid producing cultures</b>		
[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 checked="" type="checkbox"/> Two purposes: acidification of formula <b>and</b> supplementation with probiotics	<input type="checkbox"/> For the purpose of acidification of formula <b>only</b> . Contains minimal amounts of viable bacteria.	<input type="checkbox"/> For the purpose of supplementing with probiotics <b>only</b>
<b><i>Because there are some products compatible with both options on the market, and we shouldn't ignore any of them</i></b>		
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).		
<b>To gather all optional ingredients together, In our view, this should be captured as two separate clauses within the Optional IngredientsSection (Section 3.3.2).</b>		

Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.

- The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence
- Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria
- For the purpose of producing acidified formulas
- Non-pathogenic lactic acid cultures may be used

**OR**

- No additional wording is required. Alignment with the Codex Infant Formula Standard

*Please provide justification for your response and any proposed draft text:*

**The objective is to remind all the important specificities currently required for the probiotics To ensure the safety and security of this adjunction in the FUF and we we tick that proposal:**  For the purpose of producing acidified formulas, to underline the purpose of the option 1

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

### Proposed approach

#### Mandatory (core) composition

Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is :

- Evidence to support nutritional issues for young children of global concern;
- Contribution to the overall nutritional quality/integrity of the product;
- The contribution of key nutrients from cows milk for equivalence; and
- The strength of committee support for including in the core composition.

*Answer:*

**We support fully this proposal**

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:*

To guarantee this food safety and efficacy, most principles should be respected, and setting a minimum number of principles is not obvious, but the adoption of flexibility, and less prescriptive approach, supports the level of this modification of the mandatory composition at the national level.

### **Voluntary Nutrient Additions**

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

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

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

#### **QUESTION:**

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

#### **Answer:**

***This is a scientific evidence based approach supported by Morocco. the core set of mandatory nutrients could be modified at the national level by adding others nutrients based on the role of the nutrient, its' intakes and the nutritional status of the population 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,***

#### **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:*

**Morocco support the revised mandatory (core) composition of follow-up formula for young children in line with its' young children needs,**

### **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:**

**Agree with this approach**

**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:*

***This bullet point 2 is restrictive, because some optional ingredients are not part of human milk (For example some probiotics...), Thus, we suggest to replace the sentence. So the additional nutrients should be aligned with the nutrient level permissions in follow-up formula for older infants (6-12 months)***

**QUESTION:**

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

**Answer:**

*Please provide justification for your answer:*

**Agree to delete the third bullet point to avoid an overconsumption of milk as vehicle of many supplements and encourage the introduction of the right complementary food.**

**Energy contribution from macronutrients**

**Energy contribution from macronutrients**

Please provide comment and justification as to whether it is necessary to define specific macronutrient percentage contribution to overall energy.

**Answer:**

**As milk has an important contribution in the food balance of these children, it is important to consider the balance in term of macronutrients' energy**

## Energy

### Energy

Members of the eWG have recommended that the energy density of follow-up formula for young children should be established, and the following levels proposed:

#### Energy

Unit	Minimum		Maximum
kcal/100 ml	[60]	[45]	[70]
kJ/100 ml	[250]	[188]	[293]

Should the range for the energy density of follow-up formula for young children accommodate the energy content of full fat cows' milk *and* reduced fat cows' milk, or align with the minimum energy density of follow-up formula for older infants?

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

**Energy range of 45-60 kcal/100 mL is considered appropriate based on both the reference to cow's milk as well as to making a relevant contribution of approximately 15-22% of the daily dietary energy intake of young children.**

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:*

**Taking into account the varying role of this product in the food balance of young children, establishing a maximum and minimum energy level is a good compromise to correspond to the need of most populations, and to be an appropriate food for young children with different nutritional status**

## 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*

**Considering the various amount of milk intake in this group, the access to complementary food, FUF for young children is more a matter of giving the good level of calcium and micronutrients, and there is no scientific evidence for identifying a minimum and maximum level of protein. But considering the progression of obesity among these population, and by respect to the principle of security and safety, it is reasonable to identify a GUL of protein which could be the current level of protein in cows' milk.**

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 **Young children have various source of protein, but considering the nutritional objectives of FUF for young children, this food should have an ideal composition with maximum guarantees. For this reason, we need to identify the protein compositional requirement for the standard follow up formula for YC, within the current Follow-up formula standard.***

**Otherwise, no indication for hydrolysed protein in normal children, and the same position for the incoming protein from plants than the FUF for old infant.**

## 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 checked="" 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

*Please provide justification for your answer*

**Reduced fat cows' milk during the first 36 months is not recommended, In agreement with EFSA 2013 range and FOF OI**

Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?

<input checked="" 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
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*Please provide justification for your answer*

**In agreement with EFSA 2013 range**

## 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,  $\alpha$ -linolenic acid and phospholipids be established for follow-up formula for young children? Please stipulate what these levels should be; min, max, GUL.

*Please provide justification for your answers.*

**Cows' milk is insufficient in linoleic acid,  $\alpha$ -linolenic acid , we should indicate a**

**minimum level and GUL in FUF YC**

Should a range for the ratio of linoleic:  $\alpha$ -Linolenic acid be established for follow-up formula for young children?

Yes

Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG?

Yes

No

Alternative, please specify and provide justification for your answer.

**Levels should be established for: minimum  $\alpha$ -linolenic acid.**

**· Alpha-linolenic acid minimum value: 44mg/100kcal (derived from application of 0.4% total daily energy AI to equivalent % energy in product).**

**· No minimum level needed for linoleic acid when a ratio is established**

No

Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?

Yes

**<3% of total fat content**

**This is due to the UL set for children by FAO, which corresponds to < 1% energy (FAO 2010). Considering that around 30% of the energy from the diet is coming from fat, this corresponds to 3% of total fat content.**

Should this level be  $\leq 20\%$  of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk?

Yes

No

Alternative, please specify and provide justification for your answer.

No

Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
<input type="checkbox"/> Yes Please state what the maximum level should be, and provide justification for your answer.	<input checked="" 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> <b>Yes, these young children should be protected as much as old infant, because they will be exposed to such fat in their environment</b>	

## Carbohydrates

<b>Total Available Carbohydrates</b>	
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 checked="" type="checkbox"/> No
<i>Please provide your rationale:</i> <b>It will be based on residual energy</b>	
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 checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<i>Please provide your rationale:</i> <b>We have to avoid to have a sweet test as much as possible, and if minimum level of Protein and fat are chosen, we can have a higher percentage of free sugar tasting sweeter</b>	
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

Please provide your rationale:

**For the principle of flexibility and being less prescriptive**

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

Yes

No (please specify your alternative).

Please provide your rationale:

**It should be reflected on the basis of the levels of fat and protein of the current FUF YC**

### Carbohydrates footnote

#### Free sugars

While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.

Proposed Codex FUF-OI Standard

Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.

IEG 2015

Sugars other than lactose should be  $\leq 10\%$  of total carbohydrates or 5% of total energy content

An alternative level (please specify)

Please provide your rationale:

**These children are having a complementary food always rich on free sugar, and this formula is a good opportunity to adjust their taste and intake**

#### Lactose

Proposed Codex FUF-OI Standard and Codex IF Standard

Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.

IEG 2015

The main source of carbohydrates should be lactose, which should provide not less than 50% of total carbohydrates, equivalent to 4.5 g/100 kcal.

Please provide your rationale:

**The same reason above**

#### Other permitted carbohydrates

Proposed Codex FUF-OI Standard

IEG 2015

Oligosaccharides, glucose

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).	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.	
<p><i>Please provide your rationale:</i>  <b>We have to be cautious, because Milk is an important food at this level, so, The formula should be gluten free, and should not contain any ingredient which could arise the risk of allergy, food disease or any other risk</b></p>		

## Iron

Iron			
While a consensus was reached on the minimum compositional requirements for iron infollow-up formula for young children, there were differing opinions on a maximum or GUL.			
<b>Iron</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 kcal	1.0	[2.0]	[3.0]
mg/100 kJ	[0.25]	[0.3]	[0.7]
Should a maximum level or GUL be established for iron?			
<input checked="" type="checkbox"/> Yes, a maximum level should be established		<input type="checkbox"/> No	
<input type="checkbox"/> Yes, a GUL level should be established			
<p><i>Please provide your rationale:</i>  <b>The inclusion of iron is mandatory in the FUF for young children, all epidemiologic data and scientific evidence base is supporting this, 1-2 mg/100 Kcal is an effective range, regarding the amount of milk consumption in this population and their nutritional need. And, as fortified food are available in many countries, It is safer to identify a maximum than GUL level which is higher.</b></p>			
If you support establishing a maximum or GUL, please select your preferred value, providing scientific rationale to support your preferred choice.			
<input checked="" type="checkbox"/> Maximum (Proposed Codex FUF-OI) 2.0 mg/100 kcal 0.5 mg/100 kJ		<input type="checkbox"/> GUL (IEG 2015) 3.0 mg/100 kcal 0.7 mg/100 kJ	
<input type="checkbox"/> Alternative value (please provide level (max/GUL))			
<p><i>Please provide your rationale:</i>  <b>Specified in the comment above</b></p>			

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?	
<input checked="" type="checkbox"/> Yes	<input 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 checked="" type="checkbox"/> Yes	<input type="checkbox"/> No (please provide alternative values, with justification for your response)
<i>Please provide your rationale:</i>	
<b>The iron is less available from vegetable food</b>	

### Calcium

Calcium			
No consensus was reached on the requirements for calcium in follow-up formula for young children. Noting that full fat cows' milk contributes 190 mg calcium/100 kcal (range 184 - 201 mg/100 kcal) and the average amount of calcium in reduced fat cows' milk is 259 mg/100 kcal (range 240 – 280 mg/100 kcal), Please provide comment on the below options:			
Calcium Unit	Minimum	Maximum	GUL
mg/100 kcal	[50] [90] [200]	[N.S.]	[180] [NS]
mg/100 kJ	[18] [22] [24] [48]		[43]
Minimum:			
<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> <i>We don't need to specify a minimum level, because calcium is available in many foods, vegetables and at a significant level in cows' milk.</i> <i>We need to specify a <b>GUL</b>, because there is a trend to fortify more and more complementary food by adjunction of calcium. It seems that the bone metabolism of this calcium ingredient is not easy to ensure. Too much calcium could put children at risk of kidney stones and hypertension (There is scientific evidence with calcium medication in adults, some we should be cautious regarding this)</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 checked="" type="checkbox"/> Alternative value, please specify The average content in full fat cows' milk (range 184 - 201 mg/100 kcal), is closet to IEG GUL and more consistent with EFSA proposal

### Calcium

Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included?

Ratio calcium/phosphorus

Min	Max
1:1	2:1
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

*Please provide your rationale:*

At this stage, there is no scientific evidence against the current ratio or in favor of another ratio regarding a better bone growth.

### 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 <sup>x)</sup>

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]

<sup>x)</sup> 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"/> Current Codex FUF Std & proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	<input type="checkbox"/> IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	<input 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:*

**Vitamin A insufficiency is a public health issue in many countries, it is important to set a minimum level**

#### Maximum

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

**Because diet diversification provides provitamin A carotenoid sources, toxicity should not occur,**

unless we give children chronic Vit A supplement or multivitamins pills.  
**The GUL is more appropriate for these population**

**GUL**

WHO/FAO GUL of 3-5 times minimum  
 200 µg RE/100 kcal  
 54 µg RE/100 kJ

IEG 2015  
 180 µg RE/100 kcal  
 43 µg RE/100 kJ

*Please provide your rationale:*  
 Comment above

Do you support the footnote below, agreed to by the Committee for follow-up formula for older infants (REP16/NFSDUE Appendix III)?

<sup>x)</sup> 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:*  
***Vit D deficiency is a problem in this age group even in sunny country (skin color, type of cloths...), the level of the proposed FUF OI is suitable***

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:*  
***As guidance, to avoid any exaggerate adjunction, a GUL is indicated,***

**Zinc**

**Zinc**

Do you support that mandatory addition of zinc to follow-up formula for young children?

Yes  No

If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.

*Answer:*  
***As we adding iron, it makes sens to add Zinc, to align with the minimum level of current proposed FUF OI (0.5 mg% kcal), which is scientifically suitable for good***

## metabolism iron/zinc

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

*Answer:*

***For the same reason than a FUF OI, we suggest the same GUL which is safe and suitable in avoiding the technical issues***

## Vitamin C

### Vitamin C

Do you support that mandatory addition of vitamin C to follow-up formula for young children?

Yes

No

If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.

*Answer:*

**Vit C is an important ingredient, to prevent the loss of this vitamin during the storage of this food, it is desired to align to the FUF OI 10 mg%Kcal**

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

*Answer:*

***It is not in excess in diversified diet, and we suggest a precautionary approach and aligned with the current suggested FUF OI GUL 70mg%Kcal***

## Vitamin B12

### Vitamin B12

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

Yes

No

If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.

*Answer:*

**AS intakes of 0.9 ug vitamin B12 per day was adequate for the majority of young children (12-36 months) based on the WHO/FAO and several other RASBs including the IOM, EFSA, NIH, and NHMRC/MoH.**

**We suggest aligning with the current FUF OI, which is almost 15% of the adequate intake.**

Please state whether vitamin B12 should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.

*Answer:*

**For the principle of being less prescriptive and flexible, we suggest the GUL which could be the reduced fat cows' milk level, which is still less than twice the RDI level**

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## Riboflavin

<b>Riboflavin</b>	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
<input checked="" 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: 80 Ug%Kcal which is almost 15% of RDI (WHO/FAO)</i>	
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.	
<i>Answer: Aligning with the principle of being flexible and less prescriptive, we should have a GUL which could be equivalent to the reduced cows' milk level</i>	

## Sodium

<b>Sodium</b>	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.	
<i>Answer: No because, the intake is much higher than the need, and sodium level of complementary food is always to high</i>	
Please state whether sodium should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
<i>Answer: We could identify a GUL, being less prescriptive and flexible we suggest the level of full fat cows' milk (64-72mg%Kcal) which is lower than the IEG 15 level (75mg%Kcal)</i>	

## SCOPE & LABELLING

Morocco is preparing a final position for the 38th CCNFSDU meeting, giving consideration to the local context.