

# REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156-1987)

(Chaired by New Zealand and co-chaired by Indonesia and France)

## First Consultation Paper Submitters Response Form

June 2016

Please respond by **19<sup>th</sup> July 2016**

To: [Jenny.Reid@mpi.govt.nz](mailto:Jenny.Reid@mpi.govt.nz); [Alice.STENGEL@dgccrf.finances.gouv.fr](mailto:Alice.STENGEL@dgccrf.finances.gouv.fr); [codexbpom@gmail.com](mailto:codexbpom@gmail.com)

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

Name of Member Country/Organisation: **Russian Federation**

### 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:			
<b>Protein Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100 kcal	[1.8] or [1.65]	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39]	[0.84] or [0.72] or [0.60]	-
Minimum			
Codex Infant Formula standard		<input checked="" type="checkbox"/>	
1.8 g /100 kcal			1.65 g /100 kcal
0.43 g /100 kJ			0.39 g /100 kJ
<i>Please provide scientific justification and applicable references to support your response: Russian Federation supports the 1.65 g /100 kcal minimum level for protein, as to our opinion it is adequate amount, needed for healthy growth and development.</i>			
Maximum			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.5 g /100 kcal	Codex IF std	EFSA	
0.84 g /100 kJ	3.0 g /100 kcal	2.5 g /100 kcal	
	0.72 g /100 kJ	0.60 g /100 kJ	
<i>Please provide scientific justification and applicable references for your response: Russian Federation supports the 3.5 g /100 kcal maximum level for protein, as to our opinion it is safe, while allowing to keep the availability of wide range of products in markets.</i>			
Footnote 6			
The majority of the eWG supported retaining elements of footnote 6.			
[ <sup>6</sup> Follow-up formula based on <del>non-hydrolysed</del> <b>intact</b> 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 <b>hydrolysed</b> protein, please state whether you think that all, or only those containing less than [2.25 g/100 kcal] should be clinically evaluated.			

<input type="checkbox"/> All formulas based on hydrolysed protein should be clinically evaluated	<input checked="" type="checkbox"/> Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated	
<i>Please provide justification for your response. Russian Federation considers, that clinical evaluation is needed to ensure safety of formulas with relatively low level of hydrolysed protein.</i>		
Regarding formulas based on <b>intact/non-hydrolysed</b> 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 <b>intact milk protein</b> .		
<input type="checkbox"/> intact milk protein	<input checked="" type="checkbox"/> non-hydrolysed milk protein	
<i>Please provide justification for your response. Russian Federation considers wording "non-hydrolysed" as differentiating hydrolysed protein better.</i>		
Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required for any formulas based on intact/non-hydrolysed milk protein?		
<input checked="" type="checkbox"/> Yes, all formulas containing 1.65-1.8 g/100 kcal require clinical evaluation	<input type="checkbox"/> Yes, all formulas containing 1.65-2.0 g/100 kcal require clinical evaluation	<input type="checkbox"/> no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal
<i>Please provide justification for your response. Russian Federation considers, that clinical evaluation is necessary to ensure adequate growth and development of older infants, when consuming formula with low levels of protein.</i>		
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 above. <b>Error! Reference source is not found.</b>		
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
<i>Russian Federation considers, that it will serve a better understanding of the document if the minimum permissible level of protein is present in the table, while the range for which clinical study is mandatory is placed in the footnote.</i>		

## Vitamin K

Vitamin K			
The Chairs propose that the following drafting of vitamin K requirements for follow-up formula for older infants is recommended for adoption by the Committee:			
<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
<i>Please comment on this proposal and provide your justification: Russian Federation supports the vitamin K level as of 4 µg /100 kcal, based on the absence of any data on adverse events due to consumption of vitamin K at this level.</i>			

## 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:			
<b>Vitamin C<sup>15)</sup></b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>

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.				
<b>Minimum levels</b>				
<input checked="" type="checkbox"/> Codex IF Standard 10 mg/100 kcal 2.5 mg/100 kJ Taking a precautionary approach and aligned with the Codex Infant Formula Standard		<input type="checkbox"/> EFSA 4 mg/100 kcal 0.96 kJ/100 kcal Based on vitamin C requirement levels established by EFSA, taking into account that complementary foods are consumed from six months.		
<i>Please provide your preferred response: Russian Federation considers this minimal vitamin C level 10 mg/100 kcal to be most appropriate, given its critical role in metabolism of many other nutrients (for example, iron, zinc) and absence of convincing data on its negative effect in this amount.</i>				

## Zinc

<b>Zinc</b>			
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			
<b>Zinc</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
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).			
<i>Please comment on this proposal and provide your justification: Russian Federation agrees with this proposal.</i>			

## Optional Ingredients: DHA

<b>Docosahexaenoic acid (DHA)</b>			
Please provide scientific justification to support your preferred value in square brackets:			
<b>Docosahexaenoic acid<sup>21)</sup></b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
% fatty acids	[-] or [0.3]	-	0.5
<sup>21)</sup> If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, [a minimum of [x% fatty acids] should be added 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.			
If added, minimum level			
<input checked="" type="checkbox"/> No minimum level specified	<input checked="" type="checkbox"/> 0.3% fatty acids	<input type="checkbox"/> Other please specify:	
<i>Please provide scientific justification for your response: Russian Federation considers, that as DHA is an optional ingredient, no minimum level should be specified;</i>			
If you indicated that a minimum DHA content was warranted if added, please specify whether this requirement should be placed footnote 21 or in the table.			
N/A			

## 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>
<i>Please provide justification for your preferred response: Russian Federation considers, that L(+) lactic acid cultures could be used for acidification of formula or for supplementation of product with organisms for the nutritional purpose.</i>		
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).		
<i>Russian Federation considers, that section 3.3.2.4 should remain and state that "L(+) producing lactic acid cultures may be used." In our opinion it covers both use of bacteria for nutritional fortification and for technological function, namely for acidification of the formula.</i>		
Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.		
<input type="checkbox"/> The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence <input type="checkbox"/> Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria <input type="checkbox"/> For the purpose of producing acidified formulas <input type="checkbox"/> Non-pathogenic lactic acid cultures may be used <b>OR</b> <input checked="" type="checkbox"/> No additional wording is required. Alignment with the Codex Infant Formula Standard		
<i>Please provide justification for your response and any proposed draft text: Russian Federation suggests, that with current wording Standard would permit use of L(+) lactic acid cultures for both nutritional and acidification purposes, not prohibiting other potential safe ways using bacteria in the formula. Current wording also captures the key concept as with regard to the safety of use of the additional ingredient.</i>		

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

### **Proposed approach**

<b>Mandatory (core) composition</b>
Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is : <ul style="list-style-type: none"> <li>• Evidence to support nutritional issues for young children of global concern;</li> <li>• Contribution to the overall nutritional quality/integrity of the product;</li> <li>• The contribution of key nutrients from cows milk for equivalence; and</li> <li>• The strength of committee support for including in the core composition.</li> </ul>
<b>Answer:</b> <i>Russian Federation considers that primary criterion in development of compositional requirements for this section of standard should be contribution of the product to nutritional needs of young children 12-36 m.o. Following factors should be taken into consideration:</i> <ul style="list-style-type: none"> <li>• <b>Contribution to nutritional needs globally</b></li> </ul>

- **Addressing global inadequacies in nutrients**
- **Taking into account cow's milk**
- **Need to maintain nutritional quality and integrity of the product**

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 of Russian Federation:*

*While detailed substantiation provided to each respective nutrient, we consider that nutrients should be considered mandatory if they serve addressing key nutritional needs and distinguish the product technically.*

*This includes:*

- *Energy*
- *Protein*
- *Fat, including individual fatty acids and saturated fat requirements*
- *Number of vitamins and minerals*

### **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:**

*Russian Federation favors approach with inclusion of optional ingredients concept and, correspondingly, does not support the proposed approach for the 'voluntary addition of nutrients'. Any addition must meet the general principles of safety, suitability etc.*

### **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.

*Russian Federation considers, that Addition of nutrient should meet general requirements with regard to safety and suitability of its use.*

### **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:** Russian Federation supports proposed above.

**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:** Russian Federation does not see the need to reference to the levels of nutrients in human milk, considering changing role of the product in the diet of the baby from 12 months onwards. However, we are of opinion that, if added, nutrient should be at reasonable and substantial (as to the role in the diet) level.

**QUESTION:**

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

**Answer:** Yes.

Please provide justification for your answer: Russian Federation considers that principles-based approach is preferable. Introduction of the list of the substances in this case would have led more to confusion than to the purposes of this standard.

## 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.

Russian Federation considers, that expression of ingredient levels in ratio to energy meets this purpose.

## Energy

### Energy

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

#### Energy

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

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

<input type="checkbox"/> FUF-older infants & full fat cows' milk 60 kcal/100ml 250 kJ/100 ml	<input checked="" type="checkbox"/> Reduced fat cows' milk (~1.5-2% fat) 45 kcal/100 ml 188 kJ/100 ml
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Russian Federation's opinion is, that reference to reduced fat cow's milk as minimum energy level and whole fat cow's milk for the maximum energy level corresponds both to the role the product might play in the diet as well as to the percentage of energy that it would contribute to in daily energy intake (15-22%).

Do you support establishing a maximum energy density for follow-up formula for young children? If so, do you have suggestions as to how this level should be derived?

**Answer:** Yes, see above.

## 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?
<i>Please provide justification for your answer: Russian Federation considers, that minimum and maximum protein requirements for FuF for young children are necessary. We consider setting maximum and minimum protein levels necessary, taking as reference: 6% of total energy for minimum level (basing on WHO safe level) 22% of total energy as maximum (derived from the level characteristic of the whole cow's milk)</i>
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.
<i>Russian Federation considers cow's milk protein as relevant reference for protein quality in this case.</i>

### Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
<input checked="" type="checkbox"/> Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	<input type="checkbox"/> Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
<input type="checkbox"/> Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	<input type="checkbox"/> Alternative value, please specify
<i>Please provide justification for your answer: Russian Federation considers, that this minimal fat level ensuring appropriate and safe fat consumption, while allowing to avoid unnecessary restrictions.</i>	
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
<i>Please provide justification for your answer: Russian Federation considers, that this maximal fat level ensuring appropriate and safe fat consumption, while allowing to avoid unnecessary restrictions.</i>	

### Lipids

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.
<i>Please provide justification for your answers. Russian Federation considers, that establishing of GUL for linoleic acid, <math>\alpha</math>-linolenic acid and phospholipids will be most appropriate to regulate these nutrients in follow-up formulas for young children.</i>

Should a range for the ratio of linoleic: $\alpha$ -Linolenic acid be established for follow-up formula for young children?	
<input checked="" type="checkbox"/> Yes  Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Alternative, please specify and provide justification for your answer.  .	<input type="checkbox"/> No
Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?	
<input checked="" type="checkbox"/> Yes  Should this level be $\leq 20\%$ of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Alternative, please specify and provide justification for your answer.	<input type="checkbox"/> No
Should a maximum 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 checked="" type="checkbox"/> Yes Please state what the maximum level should be, and provide justification for your answer.  <i>&lt;3% of total fat content  To ensure safety of FuF for 12-36 mo, it is reasonable to refer to this limit for FuF 6-12 mo.</i>	<input type="checkbox"/> No
Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (Commercially hydrogenated oils and fats shall not be used in follow-up formula) also apply to follow-up formula for young children?	
<i>Please provide justification for your answer. Russian Federation considers, that footnote 7 for the Codex Standard for Follow-up Formula for older infants (Commercially hydrogenated oils and fats shall not be used in follow-up formula) also apply to follow-up formula for young children for safety reasons.</i>	

## Carbohydrates



Total Available Carbohydrates	
Is a minimum available carbohydrate level required, if a consensus is reached on establishing minimum and maximum levels for energy, protein and total fat?	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<i>Russian Federation considers, that establishing of minimum level for available carbohydrates is not necessary as it is dictated by the ranges of other macronutrients and energy levels, if these are established.</i>	
If you support establishing a minimum available carbohydrates level, what level do you support?	
<input checked="" type="checkbox"/> Full fat cows' milk κ5 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: N/A</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: Russia Federation considers that excessive intake of carbohydrates of any type might negatively affect metabolism and compromise balanced nutrition</i>	
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?	
<input checked="" type="checkbox"/> Yes, a maximum level should be established	<input checked="" type="checkbox"/> Yes, a GUL level should be established
<i>Please provide your rationale: Please see above</i>	
If you support establishing a maximum/GUL, do you support 14 mg/100 kcal (3.3 mg/100 kJ)?	
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No (please specify your alternative).

Carbohydrates footnote		
<b>Free sugars</b>		
While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.		
<input checked="" type="checkbox"/> Proposed Codex FUF-OI Standard  Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.	<input checked="" type="checkbox"/> IEG 2015  Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	<input checked="" type="checkbox"/> An alternative level (please specify)
<b>Lactose</b>		
<input checked="" type="checkbox"/> Proposed Codex FUF-OI Standard and Codex IF Standard  Lactose and glucose polymers should be the	<input checked="" type="checkbox"/> IEG 2015  The main source of carbohydrates should be lactose,	

preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.	which should provide not less than 50% of total carbohydrates, equivalent to 4.5 g/100 kcal.	
<i>Other permitted carbohydrates</i>		
<input type="checkbox"/> Proposed Codex FUF-OI Standard  Only precooked and/or gelatinised starches gluten-free by nature may be added.  (NB Glucose polymers are preferred carbohydrates along with lactose).	<input checked="" type="checkbox"/> IEG 2015  Oligosaccharides, glucose polymers, maltodextrin and pre-cooked or gelatinised starches can be added to provide energy. Non-digestible carbohydrates and fibres that proven to be safe and suitable for the age group may be added.	<input type="checkbox"/> Something else (please specify)

## Iron

<b>Iron</b>			
While a consensus was reached on the minimum compositional requirements for iron in follow-up formula for young children, there were differing opinions on a maximum or GUL.			
<b>Iron 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 type="checkbox"/> Yes, a maximum level should be established		<input checked="" type="checkbox"/> No	
<input checked="" type="checkbox"/> Yes, a GUL level should be established			
<i>Please provide your rationale: Russian Federation considers, that iron GUL level should be established considering the level of iron deficiencies globally.</i>			
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 checked="" 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))			
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: Russian Federation considers, that separate iron GUL level should be established for soy f protein isolate formulas, because these formulas are widely used in regions, where iron deficiency is high ( i.e South-East Asia).</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)
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## 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:			
<b>Calcium Unit</b> mg/100 kcal mg/100 kJ	<b>Minimum</b> [50] [90] [200] [18] [22] [24] [48]	<b>Maximum</b> [N.S.]	<b>GUL</b> [180] [NS] [43]
<b>Minimum:</b>			
<input type="checkbox"/> Current Codex FUF standard 90 mg/100 kcal 22 mg/100 kJ		<input checked="" 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	
.			
<b>Maximum/GUL:</b>			
<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 checked="" type="checkbox"/> IEG 2015 GUL: N.S.		<input type="checkbox"/> Alternative value, please specify	

Calcium	
Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included? Ratio calcium/phosphorus	
<b>Min</b>	<b>Max</b>
1:1	2:1
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Please provide your rationale: Russian Federation considers, that to ensure good metabolism of both nutrients the ratio should be kept, keeping in mind potential contribution of the product to the diet and variability of nutrients levels in the diet of the young children coming from the other than milk component sources.</i>	

## Vitamin A

Vitamin A			
No consensus was reached on the establishment of a minimum or maximum vitamin A value. Please provide scientific rationale to support your preferred value: Vitamin A <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]
x) expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.			
<b>Minimum</b>			
<input type="checkbox"/> Current Codex FUF Std& proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	<input checked="" type="checkbox"/> IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	<input type="checkbox"/> WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ	
<i>Please provide your rationale:opinion of Russian Federation is , thatsetting the minimum requirement is justified by the deficiencies in nutrient in young children diet and potential contribution of the product to the daily intake of young children.</i>			
<b>Maximum</b>			
<input type="checkbox"/> Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	<input type="checkbox"/> Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ		
<i>Please provide your rationale:</i>			
<b>GUL</b>			
<input type="checkbox"/> WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ	<input checked="" type="checkbox"/> IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ		
Do you support the footnote below, agreed to by the Committee for follow-up formula for older infants (REP16/NFSDUE Appendix III)?			
x) expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.			
<input checked="" type="checkbox"/> Yes		<input type="checkbox"/> No	

## Vitamin D

<b>Vitamin D</b>	
Do you support that mandatory addition of vitamin D 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:Russian Federation considers, that 0,65 µg/100 kcal as sufficient minimum level assuring reasonable and safe intake of vitamin.</i>	
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.	
<i>Answer:Correspondingly, Russian Federation consider s1,3 µg/100 kcal as the level assuring safe intake.</i>	

## Zinc

<b>Zinc</b>	
Do you support that mandatory addition of zinc 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: Russian Federation considers level of 0,6 mg/kcal as appropriate considering potential role of the product in the diet.</i>	
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
<i>Answer: Russian Federation considers level of 1.7 mg/kcal as appropriate considering potential role of the product in the diet.</i>	

### Vitamin C

Vitamin C	
Do you support that mandatory addition of vitamin C 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: Russian Federation considers level of 8 mg/kcal as appropriate considering potential role of the product in the diet.</i>	
Please state whether vitamin C should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
<i>Answer: Russian Federation considers level of 25 mg/kcal as appropriate considering potential role of the product in the diet.</i>	

### Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
<i>Answer:</i>	
Please state whether vitamin B12 should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
<i>Answer:</i>	

### Riboflavin

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

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
<i>Answer:</i>	
Please state whether 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:</i>	

## Sodium

<b>Sodium</b>	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.	
<i>Answer:</i>	
Please state whether sodium should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
<i>Answer:</i>	

## SCOPE&LABELLING

<b>Scope &amp; Labelling</b>
When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.
<i>Russian Federation supports differentiation of labeling requirements between age groups but reserves right to express opinion on labeling questions at a later stage of discussion.</i>
Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?
<i>Please provide justification for your answer.</i>
Are there any labelling areas where different provisions may be required for the two age groups?
<i>Please provide justification for your answer.</i>
Are you aware of further issues and/or evidence that need to be considered to inform the review of the scope and labelling section of the Codex Standard for Follow-up Formula? Please state the specific provisions within the Scope or Labelling section which would be informed by your response.
<i>Answer:</i>
Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up Formula, and if so, how and where? For example in the Scope and Labelling sections.
<i>Answer</i>

Please comment on how CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF.17 Rev 1) for 'Ending inappropriate promotion of foods for infants and young children' and the associated technical guidance document. Please be specific in your response and comment on what aspects of the resolution or guidance should be captured within the Standard for Follow-up Formula and within what subsection it should be reflected.

*Answer:*

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

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

*Answer:*