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 **19th July 2016**

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

Name of Member Country/Organisation: The Netherlands

Dear chairs of the eWG, thank you for the opportunity to submit a response on the review of the standard for follow-up formula. Below you will find our response regarding the follow-up formula for older infants (6-12 months).
Regarding follow-up formula for young children, the Netherlands supports the proposal that this type of formula is a substitute of (cow's) milk and could be distinguished from regular (cow's) milk by the conditional addition of some nutrients and the optional addition of other nutrients, in order to full fill specific needs of young children. And that for all these nutrients minimum as well as maximum levels should be set in order to prevent misleading of the consumer, guarantee a certain level of intake, and to prevent the risk of potential excessive intakes. However, we think it is difficult to set worldwide conditional nutrients to add to this type of formula, as the diet is diverse between countries and consequently the potential problem nutrients may not be the same. An example for the Netherlands is vitamin A. In the form of retinol the UL can be exceeded in the diet of young children, especially in a diet containing other retinol rich foods, like liver sausage. In the Netherlands, this liver sausage is a food commonly consumed among young children. The combination with a formula containing conditionally vitamin A in the form of retinol, may result in exceeding the UL. As such for the Netherlands, conditional addition of vitamin A in the form of retinol is not desired. Perhaps this can be overcome by defining the form of vitamin A that should or could be added, the Netherlands then prefers the addition as carotenoids. Another example may be vitamin C, with a diet containing fruits and vegetables, the addition of vitamin C to follow-up formula for young children is in our opinion not needed to be conditionally. We would like to include the dietary habits of young children, to examine what nutrients are the problem and what levels are required to fill the gaps.

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 g/100 kJ	[1.8] or [1.65] [0.43] or [0.39]	[3.5] or [3.0] or [2.5] [0.84] or [0.72] or [0.60]	- -
Minimum			
☒ Codex Infant Formula standard 1.8 g /100 kcal 0.43 g /100 kJ		1.65 g /100 kcal 0.39 g /100 kJ	
This is equal to the minimum amount in the most recent EU Directive			
Maximum			
3.5 g /100 kcal 0.84 g /100 kJ	Codex IF std 3.0 g /100 kcal 0.72 g /100 kJ	☒ EFSA 2.5 g /100 kcal 0.60 g /100 kJ	
This is equal to the maximum amount in the most recent EU Directive			
Footnote 6 The majority of the eWG supported retaining elements of footnote 6. [6)Follow-up formula based on ~~non-hydrolysed~~ **intact** milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated			
Regarding formulas based on **hydrolysed** protein, please state whether you think that all, or only those containing less than [2.25 g/100 kcal] should be clinically evaluated.			
☒ All formulas based on hydrolysed protein should be clinically evaluated		Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated	
We follow the EU and EFSA on this.			
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**.			
☒ intact milk protein		non-hydrolysed milk protein	
Non-hydrolysed seems more clear that it is the opposite of hydrolysed. However, if in future other techniques may be used to cut intact proteins, than intact will better cover what is meant.			
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?			
Yes, all formulas containing 1.65-1.8 g/100 kcal require clinically evaluation	Yes, all formulas containing 1.65-2.0 g/100 kcal require clinically evaluation	☒ no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal	
The EU has a minimum of 1.8 g/100 kcal. A statement on the need for clinical evaluation should also include how such evaluation should be conducted and when it is sufficient to accept such a product. We doubt whether it is possible to do this for specific product, but we think this should be done in a more general way.			
If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for formula based on intact/non-hydrolysed milk protein, do you support the recommendation that the minimum protein level which requires clinical evaluation is placed in the footnote, rather than in the table? See **Error! Reference source not found.** above			
☒ Yes		☐ No	

Vitamin K

Vitamin K

The Chairs propose that the following drafting of vitamin K requirements for follow-up formula for older infants is recommended for adoption by the Committee:

Vitamin K

Unit	Minimum	Maximum	GUL
mg/100 kcal	4	-	27
mg/100 kJ	1	-	6.5

For vitamin K the EU proposed a minimum of 1 mg/100 kcal, this is still the preferred value. However, we can agree with 4 mg/100 kcal, which is similar to the value in infant formula and does fall within the min-max range in recent EU legislation. The GUL is somewhat higher than EU legislation.

Vitamin C

Vitamin C

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

Vitamin C[15)]

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

[15)] expressed as ascorbic acid

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

Minimum levels

☐ Codex IF Standard 10 mg/100 kcal 2.5 mg/100 kJ Taking a precautionary approach and aligned with the Codex Infant Formula Standard	☒ EFSA 4 mg/100 kcal 0.96 kJ/100 kcal Based on vitamin C requirement levels established by EFSA, taking into account that complementary foods are consumed from six months.

We follow the EFSA opinion and EU legislation, children 6 months and over start with complementary foods, generally fruits and vegetables (good sources of vitamin C in general)

Zinc

Zinc

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

Zinc

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

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

The EU legislation has the same minimum values, we can support that. This legislation however has a lower maximum level of 1 mg/100 kcal (1.25 mg/100 kcal for soy protein isolate), we prefer to use that as GUL.

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)

Please provide scientific justification to support your preferred value in square brackets:

Docosahexaenoic acid[21)]			
Unit	**Minimum**	**Maximum**	**GUL**
% fatty acids	[-] or [0.3]	-	0.5

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, **[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		
No minimum level specified	☒ 0.3% fatty acids	☐ Other please specify:

This is the closest to the EU legislation/EFSA opinion

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.

The part of the note that competent national and/or regional authorities may deviate from the above conditions is this also true for other nutrients, and also for the min and max values in CODEX?

Optional Ingredients: L(+) lactic acid producing cultures

Optional addition L(+) lactic acid producing cultures		
[3.3.2.4 Only L(+) lactic acid producing cultures may be used]		
Several eWG members noted there are two purposes for the addition of L(+) lactic acid producing cultures referring to both the acidification of formula and supplementation with probiotics. Please indicate if you consider that the sub-Section 3.3.2.4 (Optional ingredients) should refer to one, or both types of addition.		
☐ Two purposes: acidification of formula **and** supplementation with probiotics	☒ For the purpose of acidification of formula **only**. Contains minimal amounts of viable bacteria.	☐ For the purpose of supplementing with probiotics **only**
This is in line with the EU legislation.		
If you consider that standard should allow for both types of addition, please indicate if you think that this should be captured within 3.3.2.4, or as two separate clauses within the Optional Ingredients Section (Section 3.3.2).		
Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.		
☒ 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		
There is much uncertainty on this topic, if it will be used as probiotics, it should be safe, and also scientifically proven beneficial for the infant. Above we said only for technological reasons, this makes it perhaps not necessary that the bacteria are still viable (?).		