Comments from the European Union

22 July 2016

To: Electronic Working Group, Chaired by New Zealand, Indonesia and France on the review of the standard for follow-up formula (CODEX STAN 156 – 1987)

Answers to the second consultation paper of June 2016

The comments expressed in the document do not prejudice the coordinated position officially and finally taken by the European Union when requested by the Codex Secretariat.

The European Union (EU) would like to thank New Zealand, Indonesia and France for the work on the second consultation document to prepare the review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987).

The EU's answers to the questionnaire are included in the document in Annex. Questions left unanswered were deleted to shorten the document.

Annex

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

Name of Member Country/Organisation: **EUROPEAN UNION**

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

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	
☒ Codex Infant Formula standard 1.8 g /100 kcal 0.43 g /100 kJ	1.65 g /100 kcal 0.39 g /100 kJ

Answer: The EU continues to agree with the proposal to set the minimum protein content of milk based follow-up formula at 1,8 g/100 kcal, in line with the European Food Safety Authority (EFSA)'s recommendations[1], the recently revised EU rules for infant formula and follow-on formula (Regulation (EU) 2016/127[2]) and the CODEX Infant Formula Standard (CODEX STAN 72-1981).

The EU confirms that EFSA has been requested to advise on the safety and suitability of a follow-on formula based on cow's milk intact protein with a protein content of at least 1.61 g/100 kcal. The EU agrees with the proposal of the Chairs to postpone discussions on this point until the results of the EFSA's assessment are published. EFSA's advice is expected by 31 October 2016 and the EU will be able to provide further feedback on this matter at CCNFSDU38.

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

Answer: The EU continues to support the proposal to lower the maximum protein amount of milk-based follow-up formulae to 2,5 g/100 kcal and of other formulae to 2,8 g/100 kcal, in line with the advice of EFSA and the recently revised EU rules.

[1] EFSA, 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760, http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3760.pdf

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0127&rid=1

The EU remains unconvinced by the arguments in favour of keeping the maximum amount at 3 g/100 kcal and recalls that there is no evidence of a physiological need for protein intakes at amounts of 3 g/100 kcal in infancy, and protein intakes of infants are generally well above the requirements.

Footnote 3

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

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

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

☒ insert Annex I (or refer) to the Codex Standard for Infant Formula	☐ review the levels contained within the Codex Standard for Infant Formula.

Answer: The EU agrees that the same reference protein (i.e. breast milk) should be used for the composition of Follow-Up Formula for older infants and Infant Formula and is therefore in favour of ensuring consistency with the values laid down in Annex I of the Codex Infant Formula Standard.

In this context, it should be noted that the amino acid reference pattern laid down in the recently revised EU legislation (Regulation (EU) 2016/127) was recommended by EFSA in its opinion of 2014 and is based on the analysis of indispensable and conditionally indispensable amino acids in human milk by the Scientific Committee for Food (SCF) of 2003[3], which is also in line with the values of the Codex Infant Formula Standard. A recent meta-analysis of 26 studies[4] which investigated the total amino acid profile in human milk closely corroborated the amounts of indispensable and conditionally indispensable amino acids in human milk determined by the SCF.

On the question of how to present the amino acid pattern: the EU considers that the content of Annex I of the Codex Infant Formula Standard should be duplicated in an Annex to the Follow-Up Formula Standard. This approach, which has already been followed in all cases where nutrient composition requirements for Follow-Up Formula for older infants were copied from the Infant Formula Standard, ensures that the revised Standard on Follow-Up Formula is a stand-alone document of easy accessibility for all interested parties.

On footnote 2 (conversion factor for soy protein): the EU considers that CCNFSDU will need to take a decision on the conversion factor for soy protein and reflect on the suggestion by CCMAS (to request FAO/WHO to convene an expert panel to review available literature for protein conversion factors). In this context, however, the EU would like to note that if a different conversion factor is ultimately adopted for soy protein, the recommendations for a higher protein content of soy formula are not anymore valid given that the higher values implicitly take into account a lower protein utilisation from soy. Adjustments would therefore be needed (both in the Follow-Up Formula and in the Infant Formula Standard). In this context, the EU recalls that EFSA's recommendation to retain a single conversion factor of 6,25, was mainly based on practical considerations.

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

Answer: As noted in previous occasions, the EU would support introducing a requirement for clinical evaluation for all formulae based on hydrolysed protein, in line with the requirements in EU legislation (Regulation (EU) 2016/127) and the advice of EFSA.

[3] SCF (Scientific Committee on Food), 2003b. Report of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae. Available online: http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

[4] Zhang Z, Adelman A, Rai D, Boettcher J and Lőnnerdal B, 2013. Amino acid profiles in term and preterm human milk through lactation: A systematic review. Nutrients, 5, 4800-4821

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
Answer: The EU does not have strong views on this issue. Regardless of the final choice, it is important to ensure consistency with the Infant Formula Standard, which currently refers to "non-hydrolysed" milk protein.		
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
Answer: As noted in previous occasions, the EU is of the view that there is no need to keep the requirement for clinical evaluation of formulae based on intact milk protein with a content higher than 1,8 g/100 kcal. This change was introduced in the EU by Regulation (EU) 2016/127 and is based on EFSA's advice that scientific data is now sufficient to prove the safety and suitability of all formulae manufactured from intact milk protein at these amounts. The EU reserves the right to answer to the Chair's question on formulae with a protein content of less than 1,8 g/100 kcal after the publication of EFSA's scientific advice on the safety and suitability of a follow-on formula based on cow's milk intact protein with a protein content of at least 1.61 g/100 kcal. If the formula under evaluation is considered to be safe and suitable, EFSA has been specifically asked to advise whether a level of at least 1,61 g/100 kcal would be applicable to all follow-on formulae. If this is not the case, EFSA is asked to advise on the specific criteria that need to be satisfied for the safety and suitability of such formulae to be demonstrated.		
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
Answer: The EU does not have strong views on this issue. Regardless of the final choice, it is important to ensure consistency with the Infant Formula Standard, which currently takes a different approach (the lowest protein level allowed under the requirement of clinical evaluation is spelled out in the text and not in a footnote).		

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
Answer: At this stage, the EU continues to support the value recommended by EFSA of 1 µg/100 kcal, which is based on generally accepted vitamin K requirements for infants and is the one set in Regulation (EU) 2016/127. The EU is open to further discuss the issue in CCNFSDU38 together with the other pending questions related to the composition of Follow-Up Formulae for older infants.			

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.	
Answer: At this stage, the EU continues to support the value recommended by EFSA, which is based on vitamin C requirements of infants and is the one set in Regulation (EU) 2016/127. The EU is open to further discuss the issue in CCNFSDU38 together with the other pending questions related to the composition of Follow-Up Formulae for older infants. In this context, the EU would like to note that considerations on the loss of vitamin C during shelf life are not relevant to the discussion on setting a minimum vitamin C amount in the Codex Standard (the same concerns would exist irrespective of what minimum amount is set), but rather to how wide should the range for vitamin C be. In this context, the EU notes that the GUL of 70 mg/100 kcal is sufficiently high, in any case, to establish a broad range for vitamin C that would allow operators to respect the minimum requirements.			

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).			
Answer: At this stage, the EU continues to support the GUL of 1 mg/100 kcal which is laid down in Regulation (EU) 2016/127 and would avoid intakes in excess of the existing UL set by EFSA for young children (assuming an energy intake from formula of 700 kcal/day). Taking into account that, as confirmed by the ISDI report, there is no loss of zinc in the finished product over shelf life, the range 0,5-1 seems sufficient to ensure flexibility to food business operators and to take into account analytical variability without compromising on food safety. The EU is open to further discuss the issue in CCNFSDU38 together with the other pending questions related to the composition of Follow-Up Formulae for older infants.			

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)			
No consensus was reached on the need for a minimum level, as a compromise could you accept that a statement is included in the footnote stating that national authorities can establish minimum requirements for the optional addition of DHA at their discretion. **Docosahexaenoic 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, 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.			
Yes		No	
Answer: In CCNFSDU37, the EU considered it prudent to require the mandatory addition of DHA to Follow-Up Formulae for older infants in amounts similar to those in breast milk. In the first round of consultations for the 2016 eWG, the EU was in favour of establishing a minimum DHA amount even in case of voluntary additions, in order to ensure the significance of such additions. The EU takes note of the new proposal to specify in a footnote that discretion is left to national/regional authorities on the setting of minimum levels for DHA addition, and considers that the issue should be further discussed in CCNFSDU38. If CCNFSDU agrees that flexibility can be left to national/regional authorities in setting minimum levels for DHA addition, the EU would respectfully ask that the footnote is drafted in a way that it recognizes also the flexibility of national/regional authorities to require mandatory addition of DHA.			

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**
Answer: It is the EU's understanding that while "probiotics" (i.e. live micro-organisms) are added to a product with the intention for the live micro-organisms to reach the host and confer to the host an alleged health benefit, lactic acid producing cultures are added to a formula with the intention to acidify it (a technological purpose), regardless of whether the final product contains live micro-organisms or not. The fact that some manufacturers consider consumption of acidified (via lactic acid producing cultures) formulae as beneficial to consumers should not lead to confusion on the technological purpose of the cultures addition. The EU is of the view that the text under section 3.3.2.4 was added to the Infant Formula Standard with the intention to exclusively cover this type of addition for "technological purposes". The EU considers that for the sake of consistency, the same approach should be followed in the Follow-Up Formula Standard.		

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*:* On 31 March 2016, the European Commission adopted its report on young-child formulae (in CODEX language, "follow-up formula for young children")[5]. The report was the conclusion of an analysis that included one market study, two scientific opinions from EFSA and in-depth consultations with Member States and interested parties. In the report, the Commission provided a detailed picture of the market of young-child formulae and identified a number of issues related to these products in the EU. It concluded that, on the basis of the information available, there is no need to lay down specific requirements for young-child formulae, given that the correct and complete application of the general framework of EU food law seems sufficient to adequately regulate them. The report's conclusions are based on the EU situation (both with respect to the market for these products and the legal framework applicable to them) and the EU continues to see the merits of regulating these products in the Codex Standard on Follow-Up Formula, taking into account the differences between the situation in the EU and globally. As noted in previous meetings of CCNFSDU as well as in previous consultations of the eWG, the EU sees with favour the structured approach proposed by the Chairs (mandatory (core) composition + flexibility for national/regional authorities to establish additional mandatory requirements + possibility for operators to add nutrients voluntarily under certain conditions). The EU has also sympathy for the four principles identified in the consultation paper. The EU would however like to take this opportunity to make more detailed comments on some elements of the approach presented by the Chairs, given that it did not submit comments on the first consultation paper of the eWG 2016. **On the number of mandatory requirements:** the EU finds the Chairs' proposals as too prescriptive. Considering the increased consumption of other foods in the diet of young children, it does not seem necessary to require Follow-Up Formula for young children to comply with the long list of nutrient compositional requirements described in the consultation paper. The EU would like to recall in this context that the principle of "less prescription" was identified by the eWG in 2015 and supported by CCNFSDU37. Taking into account regional variability with respect to nutrients of concerns, the EU continues to consider that the main focus of the Standard should be on those nutrients whose consumption is inadequate on a global scale (as noted by the eWG Chairs in the past, "*Iron is most consistently found to be inadequate in the diets of this age group (…);The quality of dietary fat and availability of the omega-3 fatty acids (particularly ALA and DHA) has been reported as inadequate in many countries").* The EU has also sympathy for the proposal to regulate sugar levels, and to ensure that the product contains adequate amounts of important nutrients contained in cow's milk such as calcium, riboflavin and vitamin B12 (taking into account that Follow-Up Formulae for young children tend to be consumed in replacement of cows' milk in the diet of young children). The EU is finally open to listen to scientific arguments proving that vitamin C addition is necessary in Follow-Up Formulae for young children to improve iron absorption. On the contrary, the EU does not consider it necessary to include in the mandatory (core) composition of Follow-Up Formula for young children requirements on energy and carbohydrate (provided that sugars are regulated), protein, fat (provided that the quality of dietary fat and availability of omega-3 fatty acids

[5] COM(2016) 169 final, Report From the Commission to the European Parliament and the Council on young child formulae, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0169&from=EN

are regulated), Vitamin A, Vitamin D (unless it is confirmed that it is a critical nutrient globally), Zinc and Sodium. The EU is particularly unconvinced by these proposed inclusions taking into account that, in any case, CCNFSDU37 agreed to the principle of "flexibility" for national/regional authorities (flexibility to add other nutrients to the mandatory (core) composition at national/regional level to meet specific nutritional needs).

On the levels of different mandatory nutrients: the EU has taken note of the difficulties of the eWG in finding an agreement on the levels that should be prescribed for different nutrients in the composition of Follow-Up Formula for young children.

The EU would like to recall that, since the beginning of the revision of the Standard, it has consistently argued in favour of a pragmatic approach and warned CCNFSDU of the difficulties that can arise when trying to use purely scientific considerations to justify compositional requirements for Follow-Up Formula for young children: any such effort is confronted with the necessity to make a series of assumptions (e.g. on the amount of the product consumed), which would transform the requirements into theoretical values hardly corresponding to the market reality (taking into account the differences in consumption patterns among CODEX Members or among young children of different age). In this context it should be recalled that in 2014, when asked, EFSA did not propose any compositional requirements for follow-up formula for young children.

The EU considers that two principles could constitute the basis for such pragmatic, flexible approach:

- as noted by EFSA in its scientific opinion of 2014, "*formulae consumed during the first year of life can continue to be used by young children";*
- cows' milk consumption is generally recommended for young children, although differences sometimes exist in food based dietary guidelines on whether full fat or semi-skimmed milk should be given.

Taking the above principles into account, for the nutrients in the mandatory (core) composition that are not present or present at very low amounts in cows' milk (e.g. iron), the minimum and max/GUL levels of Follow-Up Formula for older infants could be duplicated as such for Follow-Up Formula for young children. For the nutrients in the mandatory (core) composition naturally present in cow's milk (e.g. calcium) the minimum level could be set at the minimum laid down in the Standard for Follow-Up Formula for older infants, while the maximum/GUL could be set at the highest of two values: the maximum/GUL allowed for follow-up formula for older infants or the level of presence in cow's milk (the highest between full fat and semi-skimmed milk to ensure maximum flexibility in ranges). Specific comments on trans fats and sugars are provided in the dedicated answer boxes below.

On the additional nutrients that national/regional authorities could decide to include in the mandatory (core) composition at national/regional level: the EU is of the view that the Standard should include a provision specifying that national/regional authorities are allowed to lay down additional mandatory requirements in order to cater for nutritional needs of their populations (e.g. protein, vitamin A, vitamin D…), provided that such needs are substantiated by scientific evidence. The Standard should also specify that the same principles described above with respect to the setting of minimum and maximum/GUL levels would apply to these additional mandatory nutrients.

On general compositional requirements: it would be useful if the Standard made it clear that the general requirement agreed in CCNFSDU37 for follow-up formulae for older infants under point 3.1.1. is also applicable to follow-up formulae for young children ("*Follow-up formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants and young children. The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children*").

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: The EU would like to ask for further clarification of the approach proposed by the Chairs. In particular, it is not clear whether it is proposed that the text above is inserted as such in the Standard or it is required that eWG Members express a preference for one of the three bullet points.

In any case, the EU has already commented on the possibility for national/regional competent authorities to lay down additional mandatory compositional requirements. With respect to the possibility for manufacturers to voluntarily add to Follow-Up Formula for young children other nutrients permitted for Follow-Up Formula for older infants, the EU would also support the same logic described above: scientific justification is needed to prove the usefulness of the addition and the levels of formula/cow's milk should be taken as max/GUL (not the minimum given that these are voluntary additions).

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: The EU agrees with the approach proposed by the Chairs, in particular that the voluntary addition of optional ingredients to Follow-Up Formulae for young children should be based on generally accepted scientific evidence demonstrating the safety and suitability of the ingredient for use by young children.

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: See general comments and additional comments below.

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?	
☐ 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
Answer: the EU does not find it necessary to regulate the energy content of follow-up formulae for young children provided that limits are set to their sugar content.	

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?
Answer: see general comments. Protein requirements could be set at national/regional level, if necessary, in line with the above-described approach.

Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
☐ Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	☐ Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
☐ Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	☐ Alternative value, please specify
Answer: see general comments. Total fat requirements could be set at national/regional level, if necessary, in line with the above-described approach.	

Essential Fatty acids

Lipids
Based on the eWG recommendation to give consideration to the fatty acid profile of follow-up formula for young children, including maximum levels for trans fat, and noting the levels in full fat and reduced fat cows' milk, please state your preferred levels (with justification) as below: Should levels for linoleic acid, α-linolenic acid and phospholipids be established for follow-up formula for young children? Please stipulate what these levels should be; min, max, GUL.
Answer*:* see general comments. The EU considers that the Standard should regulate the quality of dietary fat and availability of ALA and DHA, whose intakes have been reported as inadequate in many countries, in line with the above-described approach. With respect to trans fats, the EU would like to ask for clarification on the statement in the discussion paper whereby "*the average amount of trans fat in both full fat and reduced fat cows' milk is higher than what is permitted in the Codex Standard for Infant Formula, the proposed Codex Standard for Follow-up Formula for Older Infants, and that recommended by the 2015 IEG*". The scientific literature at our disposal indicates that the average trans fats content of milk fat is around 3% of total fatty acids[6]. This is the reason why both the Standard on Infant Formula and the text for Follow-Up Formula for older infants agreed at CCNFSDU37 specify that "*The content of trans fatty acids shall not exceed 3% of total fatty*

[6] See for example Mansson H, 2008, Fatty acids in bovine milk fat, Food & Nutrition Research DOI: 10.3402/fnr.v52i0.1821;

acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in (…) formulae".

CCNFSDU38 should consider whether this provision is too prescriptive for normal cows' milks fortified with added vitamins/minerals. If this is the case, CCNFSDU38 should consider whether it would be sufficiently protective to only introduce the other restriction present in the Standard on Infant Formula (and also agreed for Follow-Up Formula for older infants) which states: "*Commercially hydrogenated oils and fats shall not be used in (…) formula*".

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?	
Yes	☐ No

Answer: see general comments. The EU considers that the Standard should regulate sugars and that there is no need to regulate carbohydrates amounts in general if sugars are regulated.

Carbohydrates in formulae for infants are an important source of energy and need to be regulated taking into account the contribution of the products to the infants' diet. However, energy needs and intakes of carbohydrates of young children are covered by a number of foods in their diet, so that no additional intake of carbohydrates needs to be assured and the Standard does not need to regulate carbohydrate levels. At the same time, sugar intakes of young children as well as the contribution of different products to the development of a preference for sweet tasting products are of public health concern in many parts of the world. This explains why the Standard should regulate sugars.

The EU notes that EFSA concluded in its Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre[7], that "*there is some evidence that high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain*". In 2015, WHO stated that "*there is increasing concern that intake of free sugars – particularly in the form of sugar-sweetened beverages – increases overall energy intake and may reduce the intake of foods containing more nutritionally adequate calories, leading to an unhealthy diet, weight gain and increased risk of NCDs*"[8]. The European Commission's report on young-child formulae also noted that some young-child formulae may contain levels of sugars that are generally not recommended for young children. In light of the above, and given the high prevalence of overweight and obesity in different regions of the world, the EU considers that the Standard should have specific provisions on sugars.

Two elements could be taken as a starting point for discussion in CCNFSDU38:

- The requirements for follow-up formulae for older infants and
- the possibility to lay down specific restrictions on free sugars and carbohydrate polymers that may contribute to giving products a sweet taste and are not present in cow's milk.

[7] EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 2010; 8(3):1462

[8] WHO, 2015, Guideline: Sugars Intake for Adults and Children

SCOPE & LABELLING

Scope & Labelling When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.
Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?
Answer: Given that the existing Standard on Follow-Up Formula is almost 30 years old, it would probably be more efficient for CCNFSDU to review one by one the labelling provisions laid down in the Infant Formula Standard and reflect on whether they can be transferred to the Follow-Up Formula Standard as such or whether they need adjustments taking into account the role of the product in the diet of older infants and young children. In this context, it cannot be ruled out that different provisions might need to apply to follow-up formula for older infants and follow-up formula for young children. This discussion will have to be carried out by CCNFSDU.
Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up Formula, and if so, how and where? For example in the Scope and Labelling sections.
Answer: Before taking a position on the matter, the EU would like to better understand the added value of the inclusion of such references, taking into account that CODEX Standards are not drafted to be read by consumers but to lay down provisions to protect consumers' health and ensure fair practices in the food trade.
Please comment on how CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF./7 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: the WHO Guidance on ending the inappropriate promotion of foods for infants and young children covers "*all commercially produced foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 month*s". Its recommendations have therefore a broader scope than the Standard on Follow-Up Formula. CCNFSDU will have to focus in particular on Recommendation 2 of the Guidance, which is directly relevant for Follow-Up Formulae as it states that "*Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products*". The consideration that Follow-Up Formula should, in all cases, be understood as a breast-milk substitute and that the International Code of Marketing of Breast-milk Substitutes covers, in all cases, Follow-Up Formulae seems to mark an important change in WHO's assessment of these products (in the recent WHO information note concerning the use and marketing of follow-up formula (2013), the WHO considered that the International Code applies to follow-up formula only under certain conditions)[9]. CCNFSDU should therefore, first of all, understand the rationale for this change with the help of the colleagues from WHO and, subsequently, discuss and agree on how this change should impact on the revision of the Standard on Follow-Up Formula.

[9] http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf