CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4 **CX/NFSDU 17/39/4-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Review of the *Standard for Follow-Up-Formula* (CODEX STAN 156-1987)

Comments at Step 3 (Replies to CL 2017/75-NFSDU)

Comments of Argentina, Brazil, Colombia, Ecuador, India, Japan, Nepal, New Zealand, Russia, Senegal, Switzerland, United States of America, EU Speciality Food Ingredients, Global Organization for EPA and DHA Omega-3s (GOED), Helen Keller International (HKI), International Association of Consumer Food Organizations (IACFO), International Baby Food Action Network (IBFAN), International Dairy Federation (IDF), Institute of Food Technologists (IFT), International Special Dietary Foods Industries (ISDI) and UNICEF

ARGENTINA

(i) Specific Observations

Recommendation 1:

Argentina supports a protein value of 1.8 g / 100 Kcal, a value that is reflected in draft legislation in public consultation on infant formula and follow-up formula. However, it does not object to the value proposed in the recommendation taking into account that the protein intake may be low and/or of poor quality in developing countries. Consequently, Argentina supports the inclusion of a footnote that specifies that follow-up formula containing than 1.8 g protein / 100 kcal should be scientifically substantiated in order to guarantee safety and suitability for the targeted population in the context of the local/regional diet.

The following should be considered:

1. Argentina considers that the term 'Scientifically substantiated' acknowledges that data set reviewed as basis of assessment should not be limited to clinical evaluation data. Relevant protein intake data and other considerations for the specific/relevant country need to be considered. As an illustration, the EFSA opinion on safety and suitability of formula for older infants with a protein content of at least 1.6 g / 100 kcal was based on consideration of breast milk protein levels, protein requirements and evidence from population surveys of sufficient protein intakes in Europe in addition to the clinical data from the formulation assessed.

2. Argentina supports the fact that national/regional authorities assess the scientific substantiation for a given formula in the context of the overall local/regional diet, but Codex Standards relating to products do not usually describe how the evaluation should be performed. If the Committee wishes to be more specific, considers it is important to reflect roles of authorities versus manufacturers accurately.

Indeed, when required, competent national and/or regional authorities generally assess the scientific substantiation presented by formula manufacturers. This substantiation may include data from clinical studies performed by the manufacturer itself, but it is not the role of the competent authority to perform clinical trials on specific products.

It is worth noting that, on this matter, the Infant Formula Standard is not more prescriptive than the proposed wording for formula for older infants.

3. Regarding the proposal that follow-up formula should be clinically evaluated "when needed", Argentina considers that, as a wider body of evidence becomes available, clinical evaluation may become redundant. Therefore, 'when needed' is important to reflect this.

References

EFSA-Scientific opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal. Adopted 5 April 2017.

EU-Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. 2.2.2016.

1.6 OPTIONAL ADDITION: DOCOSAHEXAENOIC ACID DHA.

Argentina supports the optional addition of DHA, although it notes the challenge of setting a global minimum and highlights the lack of scientific consensus on the mandatory link between ARA and DHA. The setting of a minimum level should be left to the consideration of national authorities due to the variability of DHA intake in the diversified diet of older infants.

Argentina does not support mandatory addition of ARA when DHA is added and therefore proposes to change footnote 20 as follows:

"If docosahexaenoic acid (22:6n-3) is added to follow-up formula, a minimum level of [13 mg/100 kcal (3.1 mg/100 kJ)] should be reached, and the addition of arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as DHA docosahexaenoic acid. The content of and eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, is optional. If eicosapentaenoic acid is added, its content 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 of their local population".

Consequently, the proposed footnote would read:

20) If docosahexaenoic acid (22:6n-3) is added to follow-up formula, the addition of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3), is optional. If eicosapentaenoic acid is added, its content 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 of their local population.

Reference

EFSA (2014) Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12:3760.

FAO/WHO 2010. Fats and Fally Acids in human nutrition. Report of an Expert Consultation. 10-14 November 2008. Geneva. FAO Food and Nutrition paper 91. Publication date: 2010 ISDI comments to 37th session of the CCNFSDU (2015) Review of the standard for follow-up formula (Codex STAN 156-1987). CXNFSDU 15/37/5-Add.1

Brenna JT, Varamini B, Jensen RG, Diersen-Schade DA, Boellcher JA,Arterburn LM. Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr 2007;85:1457-64.

EFSA (2013) Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal, 2013. 11:3408.

Koletzko B, Bhulla ZA, Cai W, et al. Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. Annals of Nutrition and Metabolism, 2013. 62:44-54.

Yuhas R, Pramuk K, Lien EL. Human milk fatty acid composition from nine countries varies most in DHA. Lipids 2006;41 :851-8

AFSSA (2010) AFSSA opinion regarding dietary nutrient recommendations for fatty acids. AFSSA - 2006-SA-0359.

Recommendation 3:

Argentina supports this recommendation.

Recommendation 4:

Argentina reiterates its previuos position to support a maximum level of available carbohydrates at 14 g/100 kcal instead of 12.5 g/100 kcal. This is aligned with several eWG member responses, expert opinions (ENA, ESPGHAN), recommendations from recognized authoritative scientific bodies (FAO/WHO, ioM, EFSA) and nutrient requirements for young children to support a level that is scientifically substantiated. this recommendation.

Argentina does not support the maximum level proposed as there is no scientific rationale for it.

In addition, the maximum carbohydrate level of 14 g/100 kcal:

- Meets all the objectives of the eWG and achieves nutritionally balanced composition for [name of product] for young children;

- Is aligned with the approach taken to set the maximum carbohydrate level in infant formula and the revised requirements for follow-up formula for older infants as specifically noted by the eWG (i.e. based on residual energy calculations once the minimum amounts of protein and fat were established);
- Does not significantly increase the potential amount of sugars other than lactose that could be added to [name of the product] for young children. Considering recommendation 5 (mono- and disaccharides are limited to 20% of carbohydrate), the difference between 12.5 g and 14 g/100 kcal is 1,5g carbohydrate, 20% of which would be 0,3 g mono- and disaccharides.

Limits for available carbohydrate and sugars should be assessed independently.

Modelling

Argentina has conducted the macronutrient modelling with the protein minimum of 1.8 g/100 kcal and fat minimum of 3.5 g/100 kcal as proposed at CCNFSDU38 and further compared to the energy (%E) from international recommendations. ANI has compared carbohydrate maximums of 12.5 and 14 g/100 kcal. ANI has also conducted modelling with a minimum protein level of 1.5 g, as previously proposed.

Table 1 shows if the maximum carbohydrate level is 12.5 g/100 kcal and the minimum protein is 1.8 g/100 kcal, the residual fat is 4.8g/100kcal (42.8% energy). Table 2 shows if the maximum carbohydrate level is 12.5 g/100 kcal and the minimum fat is 3.5 g/100 kcal, the residual protein is 4.6 g/100 kcal (18.5% of energy). Both scenarios result in much higher energy intakes from fat or protein than international recommendations and national regulations.

Hence, restricting maximum carbohydrate level at 12.5 g/100 kcal does not enable flexibility in formulating nutritionally balanced products that addresses the nutritional needs of young children globally.

TABLE 1*:* Modelling exercise showing the effect on minimum fat at different maximum carbohydrate levels when protein levels are 1.8 g/100 kcal

	Product 1		**Product 2**	
Low protein	**g/100 kcal**	**%E**	**g/100 kcal**	**%E**
Carbohydrate	12.5	50	14	56
Fat	4.8	42.8	4.1	36.8
Protein	1.8	7.2	1.8	7.2

TABLE 2: Modelling exercise showing the effect on minimum protein at different maximum carbohydrate levels when fat levels are at 3.5 g/100 kcal**.**

	Product 3		**Product 4**	
Low fat	**g/100 kcal**	**%E**	**g/100 kcal**	**%E**
Carbohydrate	12.5	50	14	56
Fat	3.5	31.5	3.5	31.5
Protein	4.6	18.5	3.1	12.5

TABLE 3: Comparison of products with carbohydrate (CHO) values of 12.5g and 14g (in TABLE 1 and TABLE 2) against international recommendations for AMDR (FAO/WHO 2002 & 2010, FAO/WHO/UNU, 2007, EFSA, 2013; IoM, 2002; Suthutvoravut et al, 2015)**.**

%E	**Product formulations**				**Recommendations for young children (1-3 years)**			
	12.5 g CHO		**14 g CHO**		**%E**			
	Product 1	**Product 2**	**Product 3**	**Product 4**	**EFSA[1]**	**IoM[2]**	**FAO/WHO**	**Suthutvoravut, 2015 / ENA[3]**
CHO	50	50	56	56	45-60	45-65	55-74[4]	36-56
Fat	42.8	31.5	36.8	31.5	35-40	30-40	35[5]	40-55
Protein	7.2	18.5	7.2	12.5	6-15	5-20	6[6]	6-10

TABLE 3 demonstrates that all products formulated with a carbohydrate level of 14 g/100 kcal is nutritionally the most suited to the AMDRs of international recommendations while maintaining the nutritional integrity. Formulations with protein levels at 1.8 g/100kcal and carbohydrate levels below 14 g/100kcal would not be aligned with daily recommendations as the % of energy from fat would result in much higher values compared to FAO/WHO, EFSA and IoM recommendations.

In this context, Argentina notes that the eWG has not taken the approach taken by other Codex Standards, such as Codex Standard for Infant Formula and Follow-up Formula, EFSA and ENA which sets maximum carbohydrate levels based on residual energy once minimum protein and fat levels are established. While this approach would actually lead to a residual carbohydrate level of 15.3 g/100 kcal, Argentina can however agree with a maximum level of 14 g/100 kcal available carbohydrates.

In conclusion, Argentina supports a maximum value of 14 g/100 kcal for available carbohydrates in [name of the product] for young children based on alignment with other regulations and expert recommendations. We do not support values lower than 14 g/100 kcal.

[1] EFSA Panel on Dietetic Products. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408.

[2] IoM (Institute of Medicine). Dietary reference intakes for energy, carbohydrate, fibre, fat, fatty acids, cholesterol, protein and amino acids. Food and Nutrition Board, Institute of Medicine. National Academies Press; 2002.

[3] Recommendations of an international expert group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy (Suthutvoravut, 2015). The repartition of energy as proposed here refers to the product while the other recommendations refer to the total diet.

[4] WHO/FAO Population nutrient intake goals for total CHO is 55-75% (WHO/FAO, 2003), with a 2007 Scientific Update suggesting a lower bound of 50% CHO from energy could also be appropriate (Mann, 2007).

[5] FAO/WHO: Total Fat AMDR for 6-24mo is reduced to 35% energy (from 40-60% energy from fat for 0-6mo infants) and for 2 -18years is 25-35%. (FAO/WHO, 2010).

[6] Based on protein requirements for young children (12-36 months) calculated from WHO/FAO/UNU protein requirements (WHO/FAO/UNU, 2007) using WHO weight-for-age growth standards (WHO, 2006). No upper limit for protein is set.

Additional comment

While Argentina's position for minimum protein is set at 1.5 g/100 kcal, the modelling exercise was conducted using the minimum protein level of 1.8 g/100 kcal as currently proposed. However, we would like to point out that at 14 g carbohydrate and 1.5 g/100 kcal, the residual fat is 4.2 g/100 kcal (acceptable macronutrient distribution ranges: fat 38%; protein 6%; CHO 56%). This is demonstrated in TABLE 4. This is similar to the residual fat (4.1 g/100kcal) when protein is set at 1.8 g/100 kcal. In so saying, both protein values (1.5 g and 1.8 g protein) do not change the outcome of the modelling exercise that highlights the need for 14 g/100 kcal for maximum of available carbohydrate.

TABLE 4: Modelling exercise showing the effect on minimum fat for low protein formulas containing 1.5 g / 100 kcal at different maximum carbohydrate levels.

Low protein	**g/100 kcal**	**%E**	**g/100 kcal**	**%E**	**g/100 kcal**	**%E**
CHO	120	48	12.5	50	14.0	56
Fat	5.2	46	4.8	44	4.2	38
Protein	1.5	6	1.5	6	1.5	6

References

CP 2. Second Consultation Paper. Review of the Standard for Follow-Uo Formula (CODEX STAN 156-1987). Chaired by New Zealand and co-chaired by Indonesia and France. June 2016.

EFSA Panel on Dietetic Products. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408.

ESPGHAN - CRD 2 (2016) Review of the standard for follow-up formula (Codex STAN 156-1987) – Comments from ESPHGAN.

FAO/WHO/UNU Expert Consultation on Protein and Amino Acid Requirements in Human Nutrition (2002: Geneva, Switzerland). Protein and amino acid requirements in human nutrition: report of a joint FAO/WHO/UNU expert consultation.

WHO technical report series ; no. 935. Publication date: 2007. FAO/WHO. Fats and Fatty Acids in human nutrition. Report of an Expert Consultation. 10-14 November 2008. Geneva. FAO Food and Nutrtition paper 91. Publication date: 2010.

IoM (Institute of Medicine). Dietary reference intakes for energy, carbohydrate, fibre, fat, fatty acids, cholesterol, protein and amino acids. Food and Nutrition Board, Institute of Medicine. National Academies Press; 2002.

J Mann, JH Cummings, HN Englyst, T Key, S Liu, G Riccardi, C Summerbell, R Uauy, RM van Dam, B Venn, HH Vorster and M Wiseman. FAO/WHO Scientific Update on carbohydrates in human nutrition: conclusions. European Journal of Clinical Nutrition. 2007:61(Suppl 1), S132–S137.

Suthutvoravut U, Abiodun PO, Chomtho S et al. Composition of follow-up formula for young children aged 12-36 months: recommendations of an international expert group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Ann Nutr Metab 2015; 67(2):119-132.

WHO Multicentre Growth Reference Study Group. WHO Child Growth Standards: Length/height-for-age, weight for-age, weight-for-length, weight-for-height and body mass index-for-age: Methods and development. Geneva: World Health Organization, 2006.

Recommendation 5:

Argentina favors having the maximum added sugar expressed as a % of energy, but for the purpose of responding to this recommendation, we support a maximum of added sugars (excluding lactose) of 20% of available carbohydrates (which is about 10% total energy). This is in line with limits on sugars level recommended by the WHO in 2015.

Argentina strongly supports restricting added sugars other than lactose and can accept the use of ‘mono- and disaccharides’ instead of the word ‘sugars’ as proposed in this recommendation in alignment with the definition of sugars in CAC/GL 2-185 Guidelines on Nutrition Labelling. However, we

find the last three sentences proposed for footnote 4 confusing and not adding value. Therefore, we suggest deleting them; footnote 4 would then read:

4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, should not exceed 20% of available carbohydrate.

Recommendation 6:

Argentina supports this recommendation without the text in square brackets.

Recommendations 7 - 8:

Argentina supports these recommendations.

Recommendation 9:

Argentina questions some aspects of the proposed text and recommends the following amendments to the proposed preamble (highlighted in bold):

“The Codex Alimentarius Commission acknowledges the need to protect and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where appropriate, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods. In addition, several of the products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, as appropriate, the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. [Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been endorsed by member states may also provide guidance to countries in this context.]

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).”

Rationale:

Argentina takes note that the approach is proposed by the Codex Secretariat after consultation and discussion with WHO.

Argentina supports the fact that the preamble refers to the consistency of the production, distribution, sale and use of formula with national health and nutrition policies.

Argentina questions the addition of the sentence “Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states *may also+ provide guidance to countries in this context.”

As the broader topic of WHO policies and Codex mandate will be considered at the next session of the Codex Alimentarius Commission (CAC41), this addition may prove premature.

If the Committee retains this sentence, reference should be limited to “Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been endorsed by member states may also provide guidance to countries in this context.”

Recommendation 10:

Argentina supports this recommendation.

Recommendation 11:

Argentina supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants – and as such would not need to be listed in this high level overview.

Recommendation 12:

Argentina supports this recommendation and considers the word “shall” instead of “should” as this is more consistent with the terminology used in the labelling section of the Standard.

Recommendation 13:

Argentina considers, in accordance with recommendation 9, to wait for progress in this matter and find a feasible solution, given that the Codex Secretariat and WHO are working to advance the concept of the Preamble. In addition, Argentina supports the deletion of provision 1.4 due to its redundancy.

Recommendation 14:

Argentina supports the text provided in the recommendation for the introductory paragraph.

Argentina does not support the use of voluntary declarations about nutrients or health claims neither in FUF for older infants nor in products for young children. According to CAC/GL 23-1997, item 1.4: “Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.”

It should be noted that the Argentine Food Code states that voluntary declarations about nutrients should refer to the serving of the food ready to use. Nevertheless, it does not define servings for infants and young children up to 36 months.

Recommendation 15:

Argentina supports this recommendation

Recommendation 16:

Argentina supports the recommendation for provisions 9.1.1 and 9.1.3.

In provision 9.1.2, Argentina does not consider the addition of the wording “or regional” necessary but is not opposed to it.

In provision 9.1.4, we support Option 1, although “*protein+” should be removed. This provision would thus read: “

9.1.4(a) If [name of animal] milk is the only source of protein [*+, the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

9.1.4(b) If *name of plant+ is the only source of protein**+, the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of plant] [protein].

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.+”

In provision 9.1.5, Argentina supports the use of the term “may”.

Recommendations 17 - 18:

Argentina supports these recommendations

Recommendation 19:

Argentina has no comments.

5.8 LABELLING – INFORMATION FOR USE

Argentina supports the inclusion of the sentence "*is not to be used as a sole source of nutrition+" in section 9.5.6 in order to ensure this product is clearly differentiated from Infant Formula and other products.

5.9 LABELLING – ADDITIONAL LABELLING REQUIREMENTS

Argentina supports most of the recommended wording but opposes the following requirements; the previsions in 9.6.2.2, 9.6.2.5 and 9.6.4 that they are more stringent than what are required on the label of Infant Formula". Argentina thinks they should be reconsidered in line with the approach taken by the label of "Infant formula".

Recommendation 22:

Argentina supports this recommendation

Recommendation 23:

Argentina supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants – and as such would not need to be listed in this high level overview.

Recommendation 24:

Argentina supports this recommendation and favours the word "shall" instead of "should" as this is more consistent with the terminology used in the labelling section of the Standard.

Recommendation 25:

Argentina considers, in accordance with recommendation 9, to wait for progress in this matter and find a feasible solution, given that the Codex Secretariat and WHO are working to advance the concept of the Preamble. In addition, Argentina supports the deletion of provision 1.4 due to its redundancy.

Recommendation 26:

Argentina agrees with the proposal, as we do not support the use of voluntary declarations about nutrients or health claims neither in FUF for older infants nor in products for young children. According to CAC/GL 23-1997, item 1.4:

"Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation."

This position is in line with WHA 63.23.

It should be noted that the Argentine Food Code states that voluntary declarations about nutrients should refer to the serving of the food ready to use. Nevertheless, it does not define servings for infants and young children up to 36 months.

Recommendation 27:

Argentina supports this recommendation.

Recommendation 28:

Argentina supports the recommendation for provisions 9.1.1 and 9.1.3.

In provision 9.1.2, Argentina does not consider the addition of the wording "or regional" necessary but is not opposed to it.

In provision 9.1.4, we support Option 1, although "*protein+" should be removed. This provision would thus read: "

9.1.4(a) If [name of animal+ milk is the only source of protein **+, the product may be labelled '*Name of the product] for Young Children Based on [name of animal] milk [protein]'.

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled '*Name of the product] for Young Children Based on [name of plant] [protein]'.

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.+"

In provision 9.1.5, Argentina supports the use of the term "may".

Recommendations 29 - 32:

Argentina supports these recommendations.

Recommendation 33:

Argentina supports this recommendation. However, we believe that provision 9.6.1. should include the following sentence: "The label shall include a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use."

Recommendation 34:

Argentina supports this recommendation.

Recommendation 35:

Argentina supports the proposal:

"*Name of product+ for young children means a product specially manufactured for use as a liquid part of the progressively diversified diet of young children.

Recommendation 36:

Argentina supports this recommendation.

BRAZIL

SPECIFIC COMMENTS

Comments on Recommendation 1:

Minim Protein Level

Brazil agrees with the conclusion of the Chairs that the EFSA Scientific Opinion (EFSA 2017) on minimum protein content of follow-up formula (FUF) for older infants cannot be generalised to non-European countries as it was based on European dietary surveys and on the assumption that a complementary food of a sufficient quality is provided.

Moreover, it is important to take into account that EFSA notes that only two intervention studies in healthy term infants had been provided by food business operator, which were not considered sufficient to allow a conclusion on the safety and suitability of a FUF with a protein content of 1.6 g protein/100kcal.

Therefore, it is not possible to conclusively state that formula containing 1.6 – 1.8 g protein/100 kcal would be appropriate at the global level.

Thus, Brazil supports the minimum limit of 1.8g/100kcal with an associated footnote indicating that follow-up formula containing 1.6 – 1.8 g protein/100 kcal should be clinically evaluated to ensure its safety and suitability. We are of the opinion that it would be more appropriate to present the minimum protein content of 1.8 g/100 kcal in the table with an associated footnote clarifying that formula containing 1.6 to 1.8 g of protein per 100 kcal should be clinically evaluated by a competent national and/or regional authority, for purposes of clarity. Nevertheless, we can agree with the Chairs proposal in order to align with the structure of IF Standard and to move forward.

Footnote 5: Minimum protein level in formula based on soy protein isolate

Brazil agrees with the current minimum of 2.25 g/100 kcal for follow-up formula based on soy protein isolate.

Footnote 6: Minimum protein level in formula based on hydrolysed protein

Brazil is still of the opinion that all hydrolysed protein based formulas should be clinically evaluated, not just those with less than 2.25 g protein/100 kcal.

The safety and suitability of infant formula containing protein hydrolysates have not been fully demonstrated. According Mennella et al, 2016[1], little research has focused on infant developmental effects, other than growth, of formulas that differ substantially in the form of protein and data suggest that

[1] Mennella JA, Trabulsi JC, Papas MA. Effects of cow milk versus extensive protein hydrolysate formulas on infant cognitive development. Amino Acids 2016 Mar;48(3):697-705. doi: 10.1007/s00726-015-2118-7. Epub 2015 Oct 26.

the form of protein in infant formula may impact cognitive development.

The EFSA Draft scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (2017) states that the safety and suitability of a specific formula manufactured from protein hydrolysates has to be established by clinical studies, following a case-by-case evaluation.

Therefore, Brazil thinks that all formulas based on hydrolysed protein should be evaluated by a competent national and/or regional authority to ensure its safety and suitability and proposes that footnote 6 should read:

[6) Follow-up formula based on non-hydrolysed milk protein containing ~~[~~less than 1.8 g~~]~~ protein/100 ~~[~~(0.43 g/100 kJ)~~]~~ kcal and follow-up formula based on hydrolysed protein ~~containing less than [2.25 g protein/100 kcal] (0.54 g/100 kJ)~~ should be clinically evaluated by a competent national and/or regional authority].

Comments on Recommendation 2:

Brazil has no specific comments with regard to the proposed minimum content. Nevertheless, for regulatory purposes, Brazil supports the proposed approach outlined by Chairs to establish minimum and GUL levels for the addition of DHA to follow-up formula for older infants.

Comments on Recommendation 3:

Brazil supports the minimum level of 3.5 g of fat per 100 kcal taking into account the rationale and modelling macronutrient scenarios presented in the consultation paper.

Comments on Recommendation 4:

Brazil supports the maximum level of 12.5g of available carbohydrate/100kcal, because it allows for greater flexibility in protein and fat formulations.

The modelling scenarios presented in the consultation paper of the eWG demonstrated that if the maximum carbohydrate content is specified at 12.5 g/100 kcal, product that is formulated at around 3.5 g/100 kcal can still be formulated with protein at levels that are lower than that found in full fat cows' milk. It was also demonstrated that moderate protein and fat levels in product for young children can be achieved at a maximum carbohydrate limit of 12 g/100 kcal.

A lower limit for available carbohydrates (12 or 12.5g/100kcal) is also important to partially limit the addition of sugars and other carbohydrates contributing to the sweet taste of the product.

Comments on Recommendation 5:

Brazil agrees that lactose should be the preferred carbohydrate in [name of product] based on milk protein. Therefore, mono- and disaccharides, other than lactose, should not be added unless needed for technological reasons.

It is fundamental to take into account the WHO (2015) recommendation to reduce the intake of free sugars to less than 10% of energy and conditionally recommended a further reduction to less than 5% of energy for both adults and children.

We are also of the opinion that it is important to limit the addition of not only mono- and disaccharides but also other carbohydrates which contribute to the sweet taste of the product as well as other non-carbohydrate ingredients with the purpose of imparting a sweet taste as they can have similar sweetening effects. However, we acknowledge that it is necessary to define "other carbohydrates contributing to the sweet taste" and "non-carbohydrate ingredients with the purpose of imparting a sweet taste" in order to implement the established limit.

We also note that the requirements for the addition of any ingredient with the purpose of imparting sweet taste should be addressed by this standard given that there has been general agreement that [name of product] for young children should not be overly sweet tasting.

Therefore, Brazil supports considering the maximum limit of 20% applicable to mono- and and disaccharides other than lactose, and other carbohydrates contributing to the sweet taste. We also agree that other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.

Comments on Recommendation 6:

Brazil agrees with recommendation 6.

Comments on Recommendation 7:

Brazil is of the opinion that a ratio for calcium-to-phosphorous is important to ensure a better absorption efficiency and adequate mineral balance. Nevertheless, considering that phosphorus is not a key nutrient in cows' milk and taking into account the contribution from the complementary feeding, Brazil can accept that this ratio is not included for [name of product] for young children.

Comments on Recommendation 8:

Brazil agrees with recommendation 8.

Comments on Recommendation 9:

Brazil supports the approach proposed by the Codex Secretariat and WHO. Regarding the wording of the text, Brazil suggests the following amendments:

*The Codex Alimentarius Commission acknowledges the need to ~~[~~**protect and support and ~~/~~recognize**~~]~~ breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where ~~[~~**necessary ~~/ appropriate~~**~~]~~, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, ~~[~~**as appropriate**~~,~~~~]~~ the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been ~~[~~**endorsed** / **supported**~~]~~ by member states ~~[~~**may also**~~]~~ provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Brazil notes that the main purpose of the International Code of Marketing of Breast-milk Substitute (1981) and WHO guidelines and policies is to protect breast-feeding from misleading promotional practices. Thus, it is important to clearly state this issue in the text.

Brazil strongly supports that the production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding as well as relevant WHO guidelines and policies and WHA resolutions that have been endorsed/supported by member states.

In relation to the format of the final Standard, we note that given that it has not yet been decided, Brazil suggests evaluating the possibility of establishing two different Codex Standards when the revision is completed, one for FUF and other for (Name of Product) for Young Children, considering the different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to the product for young children.

Comments on Recommentation 10:

Brazil agrees with recommendation 10.

Comments on Recommendation 11:

Brazil agrees with adding 'labelling' in the text of section 1.2 as the standard addresses specific labelling provisions for the product.

However, we think that there is no need of adding the term 'analytical' in the text. We understand that requirements of methods of analysis are detailed in a specific Codex Standard as well as other provisions regarding contaminants and hygiene, which are not mentioned in the text of section 1.2. Moreover, the terms 'quality' and 'safety' cover these aspects.

Thus, we suggest the following text:

1.2 This section of the Standard contains compositional, quality, safety, **and** **labelling** requirements for Follow-up Formula for Older Infants.

Comments on Recommendation 12:

Brazil is of the opinion that the term 'marketing' could be used for consistency with the Infant Formula Standard (Codex STAN 72-1981) as proposed below:

'1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard **would be accepted for marketing as** Follow-up Formula for Older Infants.'

Nevertheless, if the Committee understands that the term 'marketing' could create confusion, Brazil agrees with the following text:

'1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard **should/shall be presented as** Follow-up Formula for Older Infants.'

Brazil has no comments at this moment with regard the preferred terminology.

Comments on Recommendation 13:

Brazil agrees with recommendation 13.

Comments on Recommendation 14:

Brazil agrees with recommendation 14.

We are of the opinion that voluntary declaration/claim about nutrients and ingredients should not be permitted on FUF. The use of claims contradicts the provisions of the International Code of Marketing of Breast-milk Substitutes, as well as other WHO and WHA recommendations. It is important to avoid any type of declaration/claim that could be used as a way to promote the product and jeopardize breastfeeding. Information on the presence of specific ingredients or nutrients is available both on the list of ingredients and on the nutritional information table of the label. Moreover, the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use. Caregivers/consumers do not have the necessary knowledge to decide on the use of a formula based on claims/declarations about ingredients or nutrients.

Comments on Recommendation 15:

Brazil agrees with recommendation15.

Comments on Recommendation 16:

Brazil supports option 1 for purposes of better clarity regarding the source of protein used and in order to harmonize the name of the products.

In relation to section 9.1.5, Brazil supports the term 'shall' in line with Infant Formula Standard (Codex Stan 72-1981). We think that the phrase indicating that the product does not contain neither milk nor any milk derivative should be mandatory.

Clean copy:

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be *Follow-up Formula for Older Infants* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be

labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

9.1.5 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

Comments on Recommendation 17:

Brazil is of the opinion that the phrase 'including optional ingredients' is not necessary as the text clear states that a complete list of ingredients shall be declared:

9.2.1 A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

Brazil agrees with section 9.2.2. However, we suggest discussing the wording of section 9.2.2 since it refers only to animal and plant origin ingredients. We note that ingredients from other origins are also added to follow-up infant formula such as fungi, algae and synthetic ingredients.

Comments on Recommendation 18:

Brazil agrees with recommendation 18.

Comments on Recommendation 19:

Brazil agrees with recommendation 19. We note that this paper has been discussed at CCFL44 and that the Committee agreed to forward the proposed draft revision to CAC41 for adoption at step 8 (para. 33 of DRAFT REP 18/FL).

Comments on Recommendation 20:

Brazil supports recommendation 20 with some amendments.

We think that the sentence 'is not to be used as a sole source of nutrition' could be retained for purposes of clarity although it should be interpreted as redundant.

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9.5 Information for Use

9.5.1 ~~[~~Ready to use~~]~~ products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~[~~product~]~~ remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

~~[~~**9.5.6** The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, ~~[~~is not to be used as a sole source of nutrition~]~~ and that older infants should receive complementary foods in addition to the product.~]~~

Comments on Recommendation 21:

Brazil supports recommendation 21 with some amendments.

We suggest replacing the term 'label' for 'labelling' in the text, considering the definitions in CODEX STAN 1-1985:

'Label' means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

'Labelling' includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

The term 'labelling' covers both the label and any accompanying leaflet. We understand that the provisions of this section apply not only to labels but also to any material for the purpose of promoting its sale or disposal in accordance to WHO guidelines and policies.

Moreover, we note that the term 'labelling' is used in section 9.6 of the document. Thus, for consistency, the same term should be used in this section.

With regard to section 9.6.1 (d), we are of the opinion that it should be retained as suggested by the WHO representative in the 37a meeting of CCNFSDU. Moreover, the sentence is in accordance with recommendation 4 of WHA 69.9 - Ending inappropriate promotion of foods for infants and young children.

The text of section 9.6.2.4 should also be retained without deleting any word for consistency with the text of recommendation 4 of WHA 69.9:

'***Recommendation 4.*** *The messages used to promote foods for infants and young children should support optimal feeding and inappropriate messages should not be included. Messages about commercial products are conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Irrespective of the form, messages should always:*

(1) include a statement on the importance of continued breastfeeding for up to two years or beyond and the importance of not introducing complementary feeding before 6 months of age;

(2) include the appropriate age of introduction of the food (this must not be less than 6 months);

(3) be easily understood by parents and other caregivers, with all required label information being visible and legible.

21. Messages should not:

(1) include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages);

(2) include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast-milk, or that suggests that the product is nearly equivalent or superior to breast-milk;

(3) recommend or promote bottle feeding;

(4) convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.'

In relation to the section 9.6.4, we support the text in square brackets as it is accordance with recommendation 5 of WHA 69.9:

*'**Recommendation 5.** There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children.*

(1) The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).

(2) Companies that market breast-milk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).'

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9.6 Additional Labelling Requirements

9.6.1 ~~Labels~~ **Labelling** should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

~~[~~a) the words "important notice" or their equivalent;~~]~~

b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

~~[~~c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.~~]~~

~~[~~d) the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.~~]~~

~~[~~9.6.2 The ~~label~~ **labelling** shall have no pictures of infants and women nor any other picture[,] ~~or~~ text[,]

~~which idealizes the use of follow-up formula. The label shall have no pictures images, text~~ or ~~other~~ representation that might:

9.6.2.1 idealize the used of follow-up formula for older infants;

9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);

9.6.2.3 recommend or promote bottle feeding;

9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.~~]~~

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. **~~[In addition, the product should not be compared to breast-milk]~~**.

~~[~~9.6.4~~]~~ Products shall be labelled in such a way as to avoid any risk of confusion between infant formula,follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes **~~[,~~ and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.~~]~~**

Comments on Recommendation 22:

Brazil agrees with recommendation 22.

Comments on Recommendation 23:

Brazil agrees with adding 'labelling' in the text of section 1.2 as the standard addresses specific labelling provisions for the product.

However, we think that there is no need of adding the term 'analytical' in the text. We understand that requirements of methods of analysis are detailed in a specific Codex Standard as well as other provisions regarding contaminants and hygiene, which are not mentioned in the text of section 1.2. Moreover, the terms 'quality' and 'safety' cover these aspects.

Thus, we suggest the following text:

1.1 This section of the Standard contains compositional, quality, safety, **and** **labelling** requirements for (Name of product) for Young Children.

Comments on Recommendation 24:

Brazil is of the opinion that the term 'marketing' could be used in the text for consistency with the Infant Formula Standard (Codex STAN 72-1981) as proposed below:

'1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard **would be accepted for marketing as** (Name of product) for Young Children.'

Nevertheless, if the Committee understands that the term 'marketing' could create confusion, Brazil prefers the following text:

'1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard **should/ shall be presented as** (Name of product) for Young Children.'

Brazil has no comments at this moment with regard the preferred terminology.

Comments on Recommendation 25 - 27:

Brazil agrees with recommendations 25-27.

Comments on Recommendation 28:

Brazil supports option 1 for purposes of better clarity regarding the source of protein used and in order to harmonize the name of the products.

In relation to section 9.1.5, Brazil supports the term 'shall' in line with Infant Formula Standard (Codex Stan 72-1981). We think that the phrase indicating that the product does not contain neither milk nor any

milk derivative should be mandatory.

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9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be *[Name of Product] for Young Children* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be

labelled '[Name of Product] for Young Children based on [name of animal] milk [protein]'.

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled '[Name of Product] for Young Children based on [name of plant] [protein]'.

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

9.1.5 A product which contains neither milk nor any milk derivative **[**shall**] [**~~may~~**]** be labelled "contains no milk or milk products" or an equivalent phrase.

Comments on Recommendation 29:

Brazil is of the opinion that the phrase 'including optional ingredients' is not necessary as the text clear states that a complete list of ingredients shall be declared:

9.2.1 A complete list of ingredients [~~including optional ingredients~~] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

Brazil agrees with section 9.2.2. However, we suggest discussing the wording of section 9.2.2 since it refers only to animal and plant origin ingredients. We note that ingredients from other origins are also added follow-up infant formula such as fungi, algae and synthetic ingredients.

Comments on Recommendation 30:

Brazil supports recommendation 30 with some amendments**.** Brazil is not in favour of declaring nutrient values per serving size as it is not established for this age group.

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9.3 Declaration of Nutritive Value

The declaration of nutrition information [for [name of product] for young children] shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [~~or~~] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold [as well as] [~~or~~] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per [~~serving size and/or per~~] 100 kilocalories (or per 100 kilojoules) is permitted.

Comments on Recommendation 31:

Brazil agrees with recommendation 31. We note that this paper has been discussed at CCFL44 and that the Committee agreed to forward the proposed draft revision to CAC41 for adoption at step 8 (para. 33 of DRAFT REP 18/FL).

Comments on Recommendation 32:

Brazil supports recommendation 32 with some amendments.

In relation to section 9.5.6, we suggest the following amendments in order to make clear that the product should not replace a balanced and diversified diet and considering the consensus that it is not nutritionally necessary:

9.5.6 The label of (name of product) for young children shall include a statement that the product shall not be introduced before 12 months of age and ~~should be used as part of~~ **should not replace a balanced** diet.

Clean copy:

9.5 Information for use

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula [~~product~~]~~ remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. ~~[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]~~

9.5.4 ~~[~~The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use**~~]~~.**

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

[**9.5.6** The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and ~~should be used as part of a~~ **should not replace a** ~~[~~diversified~~]~~ [~~balanced~~] diet.~~]~~

Comments on Recommendation 33:

Brazil supports recommendation 33 with some amendments in accordance to the recommendations of WHA 69.9.

We also suggest replacing the term ‘label’ for ‘labelling’ in the text, considering the definitions in CODEX STAN 1-1985:

“Label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

“Labelling” includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

The term ‘labelling’ covers both the label and any accompanying leaflet. We understand that the provisions of this section apply not only to labels but also to any material for the purpose of promoting its sale or disposal in accordance to WHO guidelines and policies.

Moreover, the text of section 9.6 uses the term ‘labelling’. Thus, for consistency of the document, the same term should be used.

We suggest including the sentence ‘It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond’ in section 9.6.1 in line with recommendation 4 of WHA 69.9.

In relation to the section 9.6.2, we support the text in square brackets as it is accordance with recommendation 5 of WHA 69.9.

Clean copy:

9.6 Additional Labelling Requirements

~~[~~9.6.1 The ~~label~~ **labelling** of [name of product] for young children shall have no image, text or representation **~~[~~,including pictures of feeding bottles,~~]~~** that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. **It shall include a**

statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label**.]**

[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used]**.

Comments on Recommendation 34:

Brazil suggests the following definition:

- *Follow-up formula for older infants means a product, specially manufactured for use **as a substitute for breast-milk**, as a liquid part of a progressively / diversified diet for older infants when complementary feeding is introduced.*

We are of the opinion that the definition should clear state that follow-up formula is used as a substitute for breast-milk for consistency with WHO documents.

Comments on Recommendation 35:

Brazil supports the following definition:

(Name of Product) for young children means a product specially **[formulated and]** *manufactured for use as a liquid part of the* **[progressively]** **[**diversified**]** *diet of young children* **[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements].**

We are of the opinion that the sentence "*when nutrient intakes may not be adequate to meet the nutritional requirements"* can lead to the interpretation that a progressively diversified diet will not be sufficient to meet the nutritional requirements of young children and that the product would be necessary for this purpose. As previously agreed by the Committee, [name of the product] for young children is not considered nutritionally necessary. The nutritional needs of this age group can be met with a proper nutritional guidance.

We note, however, that the definition is vague as any liquid product which contributes to the nutritional needs of young children would meet this definition. Thus, we suggest revisiting this definition after the completion of compositional requirements of the product of young children in order to better define the nature of the product.

Comments on Recommendation 36:

Brazil agrees with recommendation 36.

Comments on Recommendation 37:

As a starting point of the discussion, Brazil understands that the name "*Young child milk-based (or plant-based)* beverage*"* could be used.

COLOMBIA

We refer below to the Spanish version of the document CX/NFSDU 17/39/4, REVISION OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987).

Recommendation 1:

1. Colombia affirms the minimum value of 1.8 g/100 kcal, while noting that there is scientific evidence for values lower than this.

2. Colombia supports keeping the amendment to note 5.

3. Colombia supports maintaining the value.

4. Colombia supports the combination clarifying that scientific evidence must be presented to the competent authority, i.e. the applicant is responsible for the evaluation and, where required, a clinical evaluation.

Recommendation 2:

Colombia affirms the minimum value of 16 mg/100 kcal and a GUL of 26 mg/100 kcal in agreement with the recommendations for energy and nutrients for the Colombian population.

Recommendation 3:

Colombia supports a minimum level of 3.5 g/100 kcal, as this is in line with the recommendations of experts on energy (FAO IoM).

Recommendation 4:

Colombia proposes that a maximum level of 14 g/100 kcal be established. At this level, the maximum energy of carbohydrates is equal to 56% of energy, allowing for the formulation of a nutritionally balanced product. This level is below the maximum level of carbohydrates defined in various proposals for AMDR (IoM, WHO, Lippman).

Recommendation 5:

Colombia supports option 1, but it believes that it should be expressed as 10% of the total energy in line with the WHO recommendation.

Likewise, Colombia supports a limit on the addition of non-carbohydrate ingredients that have a sweetening effect.

In addition, Colombia proposes that the crossed-out text marked in bold be omitted:

Carbohydrates

~~[Mono- and disaccharides], other than lactose, should not exceed 20% of the available carbohydrate. [Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates.] Sucrose and/or fructose [or other carbohydrates contributing to the sweet taste of [name of product]] should not be added, unless needed as a carbohydrate source. [Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]~~

Recommendation 6:

Colombia supports the recommendation, provided the text in brackets is omitted:

That CCNFSDU agree that the percentage limit for sugars [~~and other carbohydrates contributing to the sweet taste~~] is converted to an absolute amount based on the energy density (g/100 kcal and g/100 kJ) of product for young children once a decision is made on the maximum level of available carbohydrates.

Recommendation 7:

Colombia supports the establishment of a calcium-to-phosphorous ratio and a maximum value of 2:1. However, it proposes that the minimum value be verified, as excess phosphorus interferes with the processes of bone mineralisation.

Recommendation 8:

Colombia agrees with a minimum value of 1.5 and a maximum value of 4.5, bearing in mind that the most common form is D3 with an absorption rate of 50%.

Recommendation 9:

Colombia supports the use of the underlined terms in bold, but there was no consensus regarding the underlined text because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41); Colombia therefore refrains from commenting on this point:

The Codex Alimentarius Commission acknowledges the need to ***protect and support*** *breastfeeding as an unequalled way of providing the ideal nourishment for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where* ***appropriate****, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, **as appropriate,** the recommendations made in the International Code of Marketing of Breast-milk Substitute (*1981*) *and the* Global Strategy for Infant and Young Child Feeding. *Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that*

*have been [**endorsed / supported**] by member states [**may also provide**] guidance to countries in this context.*

This Standard is divided into two sections. *Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the* Codex Standard for Infant Formula (*CODEX STAN 72 – 1981*).

Recommendation 10:

Colombia supports the proposed text.

Recommendation 11:

Colombia supports the proposed text, with the clarification that the term “analytical” refers to composition, quality and safety.

Recommendation 12:

Colombia supports the phrase “shall be presented”:

1.3 Only products that comply with the criteria laid down in the provisions of this section of this *Standard* **shall be presented** as Follow-up Formula for Older Infants.

Recommendation 13:

Colombia refrains from commenting on this recommendation, as it was unable to reach a consensus regarding the WHO documents and the WHA resolutions because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41).

Recommendation 14:

Colombia refrains from commenting on this recommendation, as it was unable to reach a consensus regarding the WHO documents and the WHA resolutions because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41).

Recommendation 15:

Colombia refrains from commenting on this recommendation, as it was unable to reach a consensus regarding the WHO documents and the WHA resolutions because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41).

Recommendation 16:

Colombia supports the inclusion of the word “regional” and supports option 1.

It also supports the use of the term “may”, with the proposal that the sentence be modified as follows: “does not contain milk or milk products as ingredients”.

Recommendation 17:

Colombia supports the proposed amendment.

Recommendation 18:

Colombia supports the proposed text.

Recommendation 19:

Colombia supports the adoption of the proposed changes to the CCFL guide.

Recommendation 20:

Colombia supports the proposed change, but it believes that the crossed-out text in number 9.5.6 should be retained. In addition, it proposes that it be indicated that ***potable*** water must be used to prepare the product, as boiling requires specific conditions to ensure the potability of the water:

9.5 Information for Use

9.5.1 [Ready to use] products in liquid form may be used either directly or, in the case of concentrated liquid products [and powdered products], must be prepared with ***potable*** ~~**safe water or water that has been rendered safe by previous boiling before feeding,**~~ according to the directions for use.

Recommendation 21:

Colombia generally supports the proposed text with the following observations:

It proposes that the text in parentheses in number 9.6.2.2 be omitted.

It supports keeping the term discourage in number 9.6.2.4.

It requests clarification regarding the inclusion of the provision in number 9.6.2.5, as it is not included in CXSTAN 72; it therefore does not support or reject this text.

It proposes that the text in brackets in number 9.6.4 only include the clarification "to enable consumers to make a clear distinction between them".

Recommendation 22:

Colombia supports the proposed text.

Recommendation 23:

Colombia supports the proposed text, with the clarification that the term "analytical" refers to composition, quality and safety.

Recommendation 24:

Colombia supports the text "shall be presented":

Recommendation 25:

Colombia refrains from commenting on this recommendation, as it was unable to reach a consensus regarding the WHO documents and the WHA resolutions because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41).

Recommendation 26:

Colombia refrains from commenting on this recommendation, as it was unable to reach a consensus regarding the WHO documents and the WHA resolutions because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41).

Recommendation 27:

Colombia refrains from commenting on this recommendation, as it was unable to reach a consensus regarding the WHO documents and the WHA resolutions because some participants believe that the addition of this text is premature, as this issue is expected to be addressed more comprehensively during the next session of the Codex Alimentarius (CAC41).

Recommendation 28:

Colombia supports option 1 and the use of the term "may", with the proposal that the sentence be modified as follows: "does not contain milk or milk products as ingredients".

Recommendation 29:

Colombia supports the proposed text.

Recommendation 30:

Colombia supports the proposed text.

Recommendation 31:

Colombia supports the inclusion of the proposed changes in the Labelling Committee guide.

Recommendation 32:

Colombia generally supports the text and the proposed modifications, but it proposes that it be indicated that potable water must be used to prepare the product, as boiling requires specific conditions to ensure the potability of the water.

9.5 Information for Use

9.5.1 [Ready to use] products in liquid form may be used either directly or, in the case of concentrated liquid products [and powdered products], must be prepared with ***potable*** ~~**safe water or water that has been rendered safe by previous boiling before feeding,**~~ according to the directions for use**.** [Products in powder

form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula [product] remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. [Pictures of feeding bottles are not permitted on labels of [name of product] for young children.]

9.5.4 [The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use**]**.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened shall appear on the label.

[**9.5.6** The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] [balanced] diet.]

Recommendation 33:

Colombia supports the proposed text in number 9.6.1 and proposes that the text of number 9.6.2 be kept with the exception of the phrase “to enable consumers to make a clear distinction between them”.

Recommendation 34:

Colombia supports the proposed text.

Recommendation 35:

Colombia proposes that the last bracket be modified as follows: ‘when required’.

Recommendation 36:

Colombia supports the adoption of the name.

Recommendation 37:

Colombia proposes that the option ‘mix to prepare...’ be added to the name of the product, as not all products are ready to use (extracts and powders).

ECUADOR

(i) General comments

- Ecuador thanks the leaders of the electronic working group for preparing this document and for consolidating the 37 recommendations that cover the composition, preamble, scope, labelling and definitions for both follow-up formulae for older infants and for [name of product] for young children.
- It is essential that the “Additional Labelling Requirements” sections be harmonised with the International Code of Marketing of Breast-milk Substitutes. Thus, not only would breast milk be declared the best food for infants and young children, but the practice of breastfeeding would also be protected and encouraged.
- Finally, Ecuador believes that the translation into Spanish should be reviewed with Spanish-speaking member countries, with the aim of ensuring that the translation retains the essence of the proposed document in English and is comprehensible in all states whose official language is Spanish. This is because English was the language used in the working group.

(ii) Specific comments

Recommendation 1

After reviewing the information sent by the participants, Ecuador does not believe that there is solid evidence to support the reduction of the minimum protein minimum to 1.6 g/100 kcal. Accordingly, it accepts the specification regarding the evaluation by a competent national and/or regional authority.

In addition, Ecuador agrees with paragraph 6, as it establishes that follow-up formulae for infants based on hydrolysed proteins must be evaluated clinically.

Recommendation 2

Ecuador approves the decision that specifies that the levels of DHA used can be established by the competent national and/or regional authorities. However, Ecuador believes it is important to include information in the footnote indicating that it has also been established that – as an optional ingredient – it must be added in an amount associated with evidence that supports the desired effect of the addition.

Recommendation 5

Ecuador is pleased that the limit has been harmonised with the WHO recommendation to limit the contribution of free sugars to no more than 10% of total energy intake.

Recommendation 9

It believes that it is important for the Codex Alimentarius Commission to affirm the need to protect and support breastfeeding as an unequalled way of providing the ideal nourishment for the healthy growth and development of infants, rather than simply recognising this.

Recommendation 20

Section 9.5.1 should keep the note that "Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation". In addition, section 9.5.6 should keep the text indicating that the product "is not to be used as a sole source of nutrition".

Recommendation 21

For Ecuador, it is essential that the standard on breast-milk substitutes not only recognise that breast milk is the best food for infants and small children, but that it also protect and encourage the practice of breastfeeding. It wants to ensure that the standard facilitates the provision of adequate information to users of these products so they can make informed decisions and that it does not discourage or devalue the practice of breastfeeding. In this respect, Ecuador hopes that this section will be made consistent with the International Code of Marketing of Breast-milk Substitutes and it proposes that the following option be added:

9.6 Additional labelling requirements

9.6.1 Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) [a) the words "important notice" or their equivalent;]

b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

[c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]

d) the statement; "**Breastfeeding exclusively is recommended from birth to 6 months of age; breastfeeding should continue until two years of age or beyond.** The use of this product must not replace breast milk and lead to cessation of continued breastfeeding".

9.6.2 The label shall have no pictures of infants and women **(including pregnant women)**, nor any other picture or text which idealises the use of **follow-up formulae**. The label shall have no pictures images, text or other representation that might:

9.6.2.1 suggest its use for infants under the age of 6 months (including references to milestones and stages);
9.6.2.2 recommend or promote bottle feeding;
9.6.2.3 undermine or discourage breastfeeding, that makes a comparison to breast milk, or suggests that the product is nearly equivalent to or superior to breast milk;
9.6.2.4 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

9.6.3 The terms "humanised", "maternalised" or other similar terms shall not be used. **In addition, the product should not be compared to breast milk.**

9.6.4 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes.

Recommendation 32

Ecuador believes it is essential that the note in section 9.5.1 stating that “products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation” be retained.

It believes it is even more important to retain the prohibition in section 9.5.3 that states that “pictures of feeding bottles are not permitted on labels of [name of product] for young children.”

Recommendation 33

Based on the reasons given in the observation on recommendation 21, Ecuador believes that it is essential to include the following option for section 9.6:

9.6 Additional labelling requirements

9.6.1 Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) [a) the words “important notice” or their equivalent;]

b) the statement “Breast milk is the best food for your baby” or a similar statement as to the superiority of breastfeeding or breast milk;

[c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]

d) the statement; “**Breastfeeding exclusively is recommended from birth to 6 months of age; breastfeeding should continue until two years of age or beyond.** The use of this product must not replace breast milk and lead to cessation of continued breastfeeding”.

9.6.2 The label shall have no pictures of infants and women **(including pregnant women)**, nor any other picture or text which idealises the use of **(name of product) for young children**. The label shall have no pictures images, text or other representation that might:

9.6.2.1 suggest its use for infants under the age of 6 months (including references to milestones and stages);
9.6.2.2 recommend or promote bottle feeding;
9.6.2.3 undermine or discourage breastfeeding, that makes a comparison to breast milk, or suggests that the product is nearly equivalent to or superior to breast milk;
9.6.2.4 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

9.6.3 The terms “humanised”, “maternalised” or other similar terms shall not be used. **In addition, the product should not be compared to breast milk.**

9.6.4 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes.

Recommendation 37

In view of the fact that this is a ready to use drink, Ecuador believes that the product should be called: [Liquid/powder] preparation formulated for young children based on a [protein source].

INDIA

Appendix II

A. General Comment:

1. India is of the view that Follow-up Formula is not necessary and is unsuitable when used as a breast milk replacement from six months of age onwards. The same is also observed by WHO (WHO 2013: Information concerning the use and marketing of follow-up formula).

2. Alignment of the Codex standards with World Health Assembly Resolution 69.9 (2016) and the accompanying guidance: It is essential that there is policy alignment between Codex instruments and the norms, standards, resolutions and recommendations adopted by the World Health Assembly, especially those relating to infant and young child feeding. This is essential for the protection of optimal infant and young child health and to support WHO infant and young child feeding recommendations. The decisions made at the WHA by Member States need to be imbedded into Codex standards and national legislation.

Any Codex standard covering products targeted to children less than 36 months must at the very least conform to WHA Resolution 69.9 (2016) and accompanying guidance (2016).

3. Further, these formulations should meet the relevant National policy regulations.

4. Also, Follow-up Formula should not replace the culturally acceptable complementary foods.

B. Specific Comments

1. [Preamble]

India would like to revise the preamble as under

The Codex Alimentarius Commission acknowledges the need to protect and support **/ ~~recognize~~] breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants** and young chidlren**. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, ~~where [necessary / appropriate],~~ as a substitute for human milk in meeting the normal nutritional requirements of infants. ~~provided they are prepared under hygienic conditions and given in adequate amounts~~. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods. ~~and~~ These products should not ~~discourage~~** replace **breastfeeding. The production, distribution, sale and use of follow-up formula for older infants and** follow-up formula **for young children** should only be permitted if it is **~~be~~ consistent with national health and nutrition policies and relevant national/regional legislation, and** the marketing of these products must be in accordance with **~~take into account, [as appropriate,]~~ the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding**, and **relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions*. ~~that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.~~ This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).**

*(to be added in the foot note the following WHA resolutions)

- WHA Resolution 39.28 (1986) - World Health Assembly resolution in 1986 stated, “the practice being introduced in some countries of providing infants with specially formulated milks (so-.- called ‘follow-.-up milks’) is not necessary.”(http://www.who.int/nutrition/topics/WHA39.28_iycn_en.pdf)
- WHA 55.25 (2002) - the Global Strategy for Infant and Young Child Feeding, which confines the baby food companies’ role to - Ensure quality of their products; and Comply with the Code and subsequent WHA resolutions, as well as national measures. (http://www.who.int/nutrition/publications/infantfeeding/9241562218/en/)
- WHA 69.9 (2016) which welcomed the WHO technical Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children. This Guidance clarified that “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 children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products” http://www.who.int/nutrition/topics/guidance-inappropriate-food-promotion-iyc-process/en/
- WHO statement (2013) on “Information concerning the use and marketing of follow-up formula” also states “WHO recommends exclusive breastfeeding for the first six months of an infant's life. Thereafter, local, nutritious foods should be introduced, while breastfeeding continues for up to two years or beyond. Follow- up formula is therefore unnecessary. In addition, follow-up formula is not a suitable substitute for breast milk, due to its content. ”See: (http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

1 [SCOPE]

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [~~should /~~ shall] be ~~presented~~ used **as] Follow-up Formula for Older Infants** subject to national regulations**.**

Rationale: The resolution WHA69.9 and Guidance on ending the inappropriate promotion of foods for infants and young children, has defined a breast milk substitute unambiguously as "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);" Hence the marketing of "Follow-up formula for older infants;" shall come under the purview of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions and this fact should be reflected in the Scope.

2 DESCRIPTION

2.1 Product Definition

2.1.1 [Follow-up formula for older infants means a product, specially manufactured for use as a liquid part of [a progressively ~~/~~diversified**] diet for older infants when complementary feeding is introduced.]**

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.2 The nutritional safety and adequacy of follow-up formula for older infants shall be ~~scientifically~~ demonstrated, through relevant convincing scientific evidence **, to support growth and development of older infants.**

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.2.4 to 3.2.6, Competent National &/or Regional authorities wishing to add **other ingredients or substances ~~may be added~~ to follow-up formula for older infants must ensure that the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated** as safe by relevant convincing scientific evidence. **~~generally accepted scientific evidence.~~**

3.2.3

Docosahexaenoic acid

India does not support the addition of DHA to the Follow-up Formula since there is no substantive scientific basis for the addition of optional ingredients like docosahexaenoic acid (DHA) as evident from following published evidence.

- A meta-analysis on the use of LCPUFA concluded, "LCPUFA supplementation of infant formulas failed to show any significant effect on improving early infant cognition. Further research is needed to determine if LC-PUFA supplementation of infant formula has benefits for later cognitive development or other measures of neurodevelopment." (Qawasmi A, Landeros-Weisenberger A, Leckman JF, Bloch MH. Meta-analysis of long-chain polyunsaturated fatty acid supplementation of formula and infant cognition. Pediatrics. 2012 Jun;129(6):1141-9)
- A Cochrane review on supplementation of the LC-PUFA in infant formula concluded, "Majority of the RCTS have not shown beneficial effects of LC-PUFA supplementation on the neurodevelopmental outcomes of term infants. The beneficial effects on visual acuity have not been consistently demonstrated. Routinwe supplementation of term infant milk formula with LC-PUFA cannot be recommended." (Simmer K, Patole SK, Rao SC. Long-chain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database Syst Rev. 2011 Dec 7; (12): CD000376.)
- Most infant formulas contain 0.2% to 0.4% total fatty acids of DHA and between 0.35% and 0.7% total fatty acids of ARA based on worldwide averages of DHA and ARA content in human milk. Brenna J.T., Varamini B,., Jensen R.G., Diersen-Schade D.A., Boettcher J.A, Arterburn L.M. Docosahexaenoic and arachidonic acid concentration in human milk worldwide. Am. J.Clin. Nutr. 2007;85:1457-1464
- The European Food Safety Authority (EFSA), in report published in the EFSA Journal 2014;12(7):3760, has explicitly stated that "There is no necessity to add arachidonic acid, eicosapentaenoic acid, non--digestible oligosaccharides, "probiotics" or "synbiotics", chromium, fluoride, taurine and nucleotides to infant and follow on formulae."

9. [LABELLING]

9.1 The name of the product

India prefers Option 2, i.e., Delete provision 9.1.4.

9.1.5

A product which contains neither milk nor any milk derivative [shall] [may] be labelled "contains no milk or milk products" or an equivalent phrase.

India supports inserting [shall].

9.2 List of Ingredients

India would like to retain “including optional ingredients” in the list of ingredients shall be declared

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. [Food additives may also optionally declare the INS number]

India suggests that the “text in the square bracket” should only be included if this is provided as an additional information. The INS number should not replace the name of the food additive; therefore, it should be in addition to the food additive name.

9.3 Declaration of Nutritive Value

d) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

India suggests that bracketed text [as well as] should be included.

e) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

India suggests that bracketed text [as well as] should be included.

9.4 Date Marking and Storage Instructions

9.4.1

India agrees with DD/MM/YYYY

9.5 Information for use

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, **and maintained at temperature not less than 70 degrees before reconstitution of the product** according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

Rationale: Reference from World Health Organization- booklet on How to prepare Infant formula in care settings.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be discarded, shall appear on the label **and in any accompanying leaflets.**

India suggest to retain the word in square bracket, i.e., [product] and also to include the information in the leaflets also.

India would like to include another para after 9.5.6 which is as under:

9.5.7 Powdered milk products are not sterile and reconstitution, storage and handling instructions should be followed carefully to prevent serious illness”.

Rationale: (Ref:WHO.Safe preparation, storage and handling of powdered infant formula: guidelines.http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf).

9.6 Additional Labelling Requirements

9.6.1 The text may be revised as under:

The products covered by this standard are breast-milk substitutes and shall be presented as such. Marketing of such products should confirm to provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions, therefore labels should not discourage breastfeeding.

Rationale: in view of the guidance on ending the inappropriate promotion of foods for infants and young children (2016) -WHA69/A69_7Add1-en.pdf developed by WHO. Since this applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 months. The guidance recommends, "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 breast 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."

India would also like to include another para after 9.6.1 (d)

9.6.1.(e) **These products are breastmilk substitutes and should be represented as such. Marketing of these products needs to be regulated as per the provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions]**

9.6.4

The text may be modified as under:

Products shall **not be cross branded with infant formula or** be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Rationale: for better clarity of the product.

India would like to add another para after 9.6.4

9.6.5

Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

Section B

SECTION B: **Follow up formula** FOR YOUNG CHILDREN

1 [SCOPE]

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] **used** be presented as] Follow Up Formula for young children.

Rationale:

The resolution WHA69.9 and Guidance on ending the inappropriate promotion of foods for infants and young children, has defined a breast milk substitute unambiguously as "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);" Hence the marketing of "Follow-up formula for older infants;" shall come under the purview of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions and this fact should be reflected in the Scope.

2 DESCRIPTION

2.1 Product Definition

2.1.1 The definition should read as under:

Follow-up Formula for young children means a product specially [formulated and] manufactured for use as a substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a part of the liquid part of the progressively diversified diet.

3 ESSENTIALCOMPOSITIONANDQUALITYFACTORS

3.1 Essential composition

3.1.1. Follow up Formula for young children.....

3.2 The nutritional safety and adequacy of **follow up formula** for young children shall be ~~scientifically~~

demonstrated **through relevant convincing scientific evidence**, to support growth and development of young children.

c. Carbohydrates

[Mono- and disaccharides], other than lactose, should not exceed ~~20%~~ **10 %** of available carbohydrate. [Mono and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.] Sucrose and/or fructose [or other carbohydrates contributing to the sweet taste of [name of product]] should not be added, unless needed as a carbohydrate source. [Other non carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]

Rationale: WHO recommends that intake of free sugars should be limited to less than 10% of total energy intake. (WHO. Guidelines: Sugar intake for adults and children. See: http://apps.who.int/iris/bitstream/10665/149782/1/9789241549028)

India supports the WHO recommendation to limit the intake of added sugars for older infants and young children based on their negative effect on body weight and dental caries. India supports that limits should be put on added sugars other than lactose accordingly.

India also opposes the addition of industrially produced carbohydrates (made from genetically modified corn), such as maltodextrin (MDX), which have been implicated in increased growth of E. coli, negatively altering the microbiome, has been linked to Chrone's Disease and diabetes related to its high glycemic index. (Nickerson KP, McDonald C (2012) Crohn's Disease-Associated Adherent-Invasive Escherichia coli Adhesion Is Enhanced by Exposure to the Ubiquitous Dietary Polysaccharide Maltodextrin. PLoS ONE7(12): e52132. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0052132https://doi.org/10.1371/journal.pone.0052132)

Fructose:The consumption of fructose rather than glucose has been linked to negative metabolic and clinical outcomes, including obesity, glucose intolerance and hepatic steatosis.

Since older infants and young children may be consuming FUF products on a daily basis, these added carbohydrates with known negative effects should not be added to these products. (Softic, E. et al. Divergent effects of glucose and fructose on hepatic lipogenesis and insulin signaling. J Clin Invest. 2017 Oct 3. pii: 94585. doi: 10.1172/JCI94585.

Calcium

India recommends that a ratio of specifying a minimum 1:1 and a maximum of 2:1 should be included.

Rationale: The proposed ration will help in optimal absorption and utilisation of both the nutrients.

Vitamin D

India recommends that if used as a part of a progressively diversified diet, the minimum value of Vitamin D may be 1 mcg/100 Kcal. The maximum value of 4.5 mcg is too high.

3.2 Optional Ingredients

3.2.1 The text may be revised as under:

In addition to the essential compositional requirements listed under 3.1.3 Section B, **Competent National and/or Regional authorities wishing to add** other ingredients, substances or nutrients ~~may be added to~~ [Follow up Formula] for young children **must ensure that** ~~where~~ the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated **as safe by relevant convincing scientific evidence**. ~~by generallyacceptedscientificevidencebygenerallyacceptedscientific evidence. by generally accepted scientific evidence. Optional ingredients listed in 3.1.3 Section A are also permitted.~~

9 Labelling

India prefers Option 2, i.e., Delete provision 9.1.4.

9.1.5

India supports inserting "shall".

9.2 List of Ingredients

9.2.1 India would like to retain "including optional ingredients" in the list of ingredients shall be declared

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. [Food additives may also optionally declare the INS number]

India suggests that the “text in the square bracket” should only be included if this is provided as an additional information. The INS number should not replace the name of the food additive; therefore, it should be in addition to the food additive name.

9.5 Information for use

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, **and maintained at temperature not less than 70 degrees before reconstitution of the product** according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

Rationale: Reference from World Health Organization- booklet on How to prepare Infant formula in care settings.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be discarded, shall appear on the label **and in any accompanying leaflets.**

India suggest to retain the word in square bracket, i.e., [product] and also to include the information in the leaflets also.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. [~~Pictures of feeding bottles are not permitted on labels of (name of product) for young children.~~]

India would like the strikethrough text should be retained. The revised text will be as under:

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product**. Pictures of feeding bottles are not permitted on labels of (name of product)** for young children.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened shall appear on the label **and in any accompanying leaflet.**

9.5.6 The label of **Follow up Formula** for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] ~~[balanced]~~ diet.]

India would like to include another para after 9.5.6 which is as under:

9.5.7 Powdered milk products are not sterile and reconstitution, storage and handling instructions should be followed carefully to prevent serious illness”.

Rationale: (Ref:WHO.Safe preparation, storage and handling of powdered infant formula: guidelines.http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf)

9.6 Additional Labelling Requirements

9.6.1 The text may be revised as under:

The products covered by this standard are breast-milk substitutes and shall be presented as such. Marketing of such products should confirm to provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions, therefore labels of Follow Up Formula for young children shall have no image, text or representation including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of Follow up Formula for young children. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label.

The text in square brackets should be included.

India would like to add another para after 9.6.2

9.6.3

These products are breast milk substitutes and should be represented as such. Marketing of these products needs to be regulated as per the provisions of the International Code of Marketing of Breast milk Substitutes and subsequent relevant WHA resolutions]

JAPAN

Recommendation 4

Japan suggests setting a maximum level of 14.0 g/100kcal for available carbohydrates.

(Rationale)

In terms of macronutrient requirements, 14.0 g/100 kcal for available carbohydrates supplies appropriate energy. As described in CX/NFSDU 17/39/4, the maximum energy from available carbohydrates of 14.0 g/100 kcal equates to 56 % of total energy, which is well within the recommendations from WHO (Mann J et al 2007), Institute of Medicine (IoM 2002) and EFSA (2013).

In terms of flexibility, we stress the approach which is stated in para 70 of REP 17/NFSDU that the standard needs to be flexible in composition. We have concerns that the protein level of 1.8 g/100 kcal and the fat level of [3.5] g/100 kcal are not served as minimum levels for fat and protein in the product formulated with a maximum level of 12.5 g/100 kcal for available carbohydrates which needs higher levels of protein and fat and that a maximum level of 12.5 g/100kcal for available carbohydrates leads to less flexibility in composition. When these minimum levels for protein (7.2 % of total energy) and fat (31.5 % of total energy) are used in formulation, the maximum level of available carbohydrates should be 15.3 g/100 kcal (61.3 % of total energy). 15.3 g/100kcal is theoretically the most appropriate level. However, considering the discussions at the last CCNFSDU, we suggest 14.0 g/100 kcal which is the closest to 15.3 g/100kcal among three values.

References

EFSA Panel on Dietetic Products. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013; 11(10):3408.

IoM (Institute of Medicine). Dietary reference intakes for energy, carbohydrate, fibre, fat, fatty acids,cholesterol, protein and amino acids. Food and Nutrition Board, Institute of Medicine. National Academies Press; 2002.

Mann J, Cummings JH, Englyst HN, Key T, Liu S, Riccardi G, Summerbell C, Uauy R, van Dam RM, Venn B, Vorster HH and Wiseman M. FAO/WHO Scientific Update on carbohydrates in human nutrition: conclusions. European Journal of Clinical Nutrition; 2007: 61(Suppl 1), S132-S137.

NEPAL

1. Recommendation 1: No Comment
2. Recommendation 2: **Can Support**

   Reasons: Nepal can support but would have liked the minimum to have been **20mg/100 Kcal** so if opened for discussion request this be reconsidered**.**
3. Recommendation 3: **Does Not Support**

   Reasons: Nepal supports a higher minimal fat level of **4g/100kcal** since such a higher fat level is essential to support child growth up to 3 years of age.
4. Recommendation 4:Support
5. Recommendation 5: Support
6. Recommendation 6: Support
7. Recommendation 7: Nocomment
8. Recommendation 8: Support
9. Recommendation 9:**Support only after the inclusion of the specific WHA resolutions 39.28, 63.23, and 69.9**

Reasons: Nepal strongly believes in protecting, promoting, and supporting breastfeeding, and in this regard the inappropriate marketing of breastmilk substitutes has hindered achieving this. Therefore, in this document, we believe that there should be explicit mentioning of the WHA resolutions **WHA 39.28, WHA 63.23, and WHA 69.9** in the Preamble as agreed at the 38th Session of CCCNFSDU meeting.

Nepal further proposes to edit the square brackets and thus, the text reads as:

*The Codex Alimentarius Commission acknowledges the need to **protect and support** breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where **necessary**, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, **~~[as appropriate,]~~** the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding**, r**elevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions **39.9, 63.23, and 69.9** that have been **supported** by member states **~~[may also]~~** provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

10. Recommendation 10:Support
11. Recommendation 11**:** Support
12. Recommendation 12:Support withtheuseof **SHALL**

Reasons: Nepal supports the word **SHALL** in the square brackets. This would prevent manufacturers to develop similar products that would bypass the standard.

13. Recommendation 13: **Does Not Support**

Reasons: Nepal reiterates that the inclusion of the reference to WHA resolutions 39.28, 63.23, and 69.9 is necessary. If not included in the Preamble then provision 1.4 must not be deleted and must refer to WHA **39.28, WHA 63.23 and WHA 69.9**.

14. Recommendation 14:Support
15. Recommendation 15: Support
16. Recommendation 16: **Support with option 2 for 9.1.4**

Reasons: Nepal supports option 2 in 9.1.4 to delete provision 9.1.4 as it is covered by 9.1.3

17. Recommendation 17: Support
18. Recommendation 18: Support
19. Recommendation 19: Support
20. Recommendation 20**: Support with choice.**

Reasons: 9.5.1: Delete 'ready to use'. All other supported.

21. Recommendation 21: **Supports with edits**

Reasons: WHA 69.9 adopted in 2016 and its associated Guidance is clear that the product is a breastmilk substitute and as such must comply with the International Code of Marketing of Breast-milk Substitutes, it is thus essential that the additional labelling requirements (9.6) must encompass all elements of the Code and be aligned with the equivalent text in the Infant Formula Standard.

9.6.1a): Nepal supports the deletion of the square brackets.

9.6.1 b): Supports the text

9.6.1 c): Supports the deletion of the square brackets.

9.6.1 d): Nepal does not support the deletion of this text.

The statement "The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding" is necessary to ensure that mothers/caregivers have right to be informed that this product is not necessary and that the use of this product may lead to the cessation of breastfeeding.

9.6.2. Although Nepal would like to have the deleted words included, but to improve the readability, it supports the existing wording.

However, as mentioned in our CPs, Nepal would like to insert the word **older infants** and therefore the text at 9.6.2 now reads as "The label shall have no pictures of infants, older infants and women nor any other picture…"

Since this standard has two categories – infants and older infants, this would not allow inclusion of pictures of either infants or older infants in the label.

9.6.2.1 - 3: Nepal supports this text.

9.6.2.4: Nepal does not support any of the proposed deletions. We have been constantly proposing in our previous CPs, that the additional labelling requirements should have text that reads “undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;”.

9.6.2.5: Nepal supports this text.

9.6.3. Nepal continues to propose to include “the products should not be compared with the breastmilk”. This statement could be, however, deleted if comparison to breastmilk is included in 9.6.2.4.

9.6.4 Nepal supports the removal of all the square brackets.

22. Recommendation 22:Support
23. Recommendation 23:Support
24. Recommendation 24:Support with the use of **SHALL**

Reasons: Nepal supports the word **SHALL** in the square brackets. This would prevent manufacturers to develop similar products that would bypass the standard.

25. Recommendation 25:**Does Not Support**

Reasons: Nepal strongly believes in protecting, promoting, and supporting breastfeeding, and in this regard the inappropriate marketing of breastmilk substitutes have hindered achieving this. Therefore, in this document, we believe that there should be explicit mentioning of the WHA resolutions **WHA 39.28, WHA 63.23, and WHA 69.9** in the Preamble.

26. Recommendation 26: Support
27. Recommendation 27: Support
28. Recommendation 28: Supportwith option 2 for 9.1.4

Reasons: Nepal supports option 2 in 9.1.4 to delete provision 9.1.4 as it is covered by 9.1.3

29. Recommendation 29:Support
30. Recommendation 30: Support
31. Recommendation 31: Support
32. Recommendation 32:**Support with Choices**

Reasons: 9.5.1: Delete ‘ready to use’. Delete all other square brackets and deleted words

9.5.2: Delete square brackets around products.

9.5.3: Delete all deleted words.

9.5.4: Delete square brackets.

9.5.5: Delete square brackets around entire text and delete square brackets around ‘diversified’

33. Recommendation 33: **Does Not Support**

Reasons: Nepal does not support the text as it stands. It is very clear that global guidance recommends exclusive breastfeeding for 6 months and continued breastfeeding for 2 years and beyond. In this context, Nepal would still prefer mothers to breastfeed (and not use breastmilk substitutes) their babies along with complementary feeding. Thus, all the additional labelling requirements that were included in the Follow-up formula for older infants should also be included in the additional requirement for (Name of product) for Young Children.

Therefore, we propose that the text in 9.6 Option 2 in the 2nd Consultation paper should be retained and further discussed.

34. Recommendation 34: **Does Not Support**

Reasons: Nepal does not support the proposed definition of Follow-up formula for older infants as this definition suggest that these products are not breastmilk substitutes.

The proposed definition implies that this product is used when complementary feeding is introduced. Does this mean that this product is not different to any other food item that is being introduced during the complementary feeding period? We would like to draw attention that FUF for older infants are fed in place of breastmilk, and therefore, by default, it is a breastmilk substitute. Hence, the definition included in the discussion documents of the eWG should be maintained which reads “Follow-up formula for older infants

means a product, specially manufactured for use **as a substitute for breastmilk** as a part of the diet for older infants when complementary feeding is introduced".

The committee writes that 15 eWG members selected this definition, and Nepal is one of them. We strongly propose that this definition should stand keeping in mind that country's like ours follow strictly to the Codex definitions. Further discussion is therefore necessary for defining follow up formula for older infants.

35. Recommendation 35: **Does Not Support**

Reasons: Nepal does not support the proposed definition of (Name of product) for Young children, since this definition considers this product not as a breastmilk substitute. Nepal reiterates that, as FUF, this product is used in place of breastmilk, and therefore, it is by default, a breastmilk substitute. Hence the definition of the products should be, as stated in our previous submissions to the eWG, as

"(Name of Product) for young children means a product, especially manufactured for use **as substitute for breast-milk** as a part of the diet for older infants when complementary feeding is introduced".

As like follow-up formula for older infants, this product functions to replace the breastmilk that the young child should be consuming. The WHA resolutions, and the IYCF practices explicitly mention consumption of breastmilk for '2 years and beyond'. This means that breastmilk is a part of the diet of children 12-36 months of age. Now, this product is used instead of breastmilk, and hence, how can this product not be termed as a breastmilk substitute?

36. Recommendation 36: Support

37. Recommendation 37: **Does Not Support**

Reasons: Nepal does not support either of the names given to the product. The term "formulated" has immense chances for mothers/caregivers to get enticed, seeing it as a product that offers benefits, resulting in replacing breastfeeding with this product, which is against the appropriate IYCF practices. Hence, we propose that the name should be, as proposed in the 2nd eWG consultation paper, "Young child milk-based (or plant-based) drink.

NEW ZEALAND

New Zealand would like to make an overarching comment that we consider that any requirements for Follow-up formula for older infants and [Name of product] for young children should not be more restrictive than in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex STAN 72-1981).

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

Recommendation 1:

1) New Zealand agrees that a minimum protein level of 1.6 g/100 kcal be established and presented in the table rather than in the footnote, and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/100 kcal for follow-up formula for older infants.
2) New Zealand agrees that the minimum protein value for soy protein isolate should be retained at 2.25g/100 kcal, and that the second sentence in footnote 5 should be amended to be consistent with the first (include 'or goats'') for follow-up formula for older infants.
3) New Zealand supports retaining the current minimum of 2.25g/protein/100 kcal for follow-up formula for older infants based on hydrolysed protein.
4) New Zealand does not support combining the two sentences in footnote 6 relating to the clinical evaluation of formula based on non-hydrolysed milk protein containing less than 1.8 g/protein/100 kcal and formula based on hydrolysed protein containing less than 2.25 g/protein/100kcal.

New Zealand is of the view that clinical evaluation of lower protein formulations (below 1.8g/protein/100 kcal) is necessary. New Zealand notes that clinical evaluation can build on previous clinical trials and does not mean that new trials will always need to be conducted, provided the evidence base for the formulation is already sufficient. New Zealand considers that it is not necessary to specify in the footnote who should conduct the clinical evaluation and notes that it is not stated in the equivalent footnote in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex STAN 72-1981).

In addition to clinical evaluation, New Zealand considers that other sources of scientific data such as data on protein intakes might be required to demonstrate the safety and suitability of the products for the appropriate population and suggest that the addition of "scientifically substantiated for the appropriate population" is appropriate in footnote 6 to address this in relation to lower protein formulations.

a) Protein 2), 3), 4)

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.6][5),6)]	3.0	-
g/100 kJ	[0.38][5),6)]	0.72	-

[2)] For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

[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 of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); 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.

[4)] Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

[5)] The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' **[or non-goats']** milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of **[**2.25 g/100 kcal (0.5**4** g/100 kJ)**]** applies.

~~[[6)] Follow-up formula based on non-hydrolysed milk protein containing [1.61 – 1.8 g] protein/100 kcal should be clinically evaluated by a competent national and/or regional authority. Follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].~~

[[6)] Follow-up formula based on non-hydrolysed milk protein containing **~~[~~less than 1.8 g~~]~~** protein/100 kcal **~~[~~(0.43 g/100 kJ)~~]~~ should be scientifically substantiated for the appropriate population** and clinically evaluated. ~~and~~ **~~f~~Follow**-up formula based on hydrolysed protein containing less than ~~[~~2.25 g protein/100 kcal~~]~~ **(0.54 g/100 kJ)** should be clinically evaluated**.** ~~by a competent national and/or regional authority.]~~

Clean copy of footnote 6:

[6)] Follow-up formula based on non-hydrolysed milk protein containing less than 1.8 g protein/100 kcal (0.43g/100 kJ) should be scientifically substantiated for the appropriate population and clinically evaluated. Follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal (0.54g/100 kJ) should be clinically evaluated.

Recommendation 2:

New Zealand agrees with recommendation 2 regarding the optional addition of docosahexaenoic acid and the minimum and GUL levels. New Zealand notes the need to correct the conversion of 30mg/100 kcal to 7.2mg/100 kJ (not 7.9 mg/100 kcal).

New Zealand would like to note that the provisions for the optional addition of docosahexaenoic acid are also carried over to [name of product] young children, including footnote 20, as per the Draft Standard Section B 3.2.1 Optional ingredients. New Zealand does not consider it necessary that should docosahexaenoic acid be added to [name of product] for young children that an equal amount or arachidonic acid would need to be added given that the progressively diversified diet of young children contains a number of sources of arachidonic acid. New Zealand would welcome discussion on the need to clarify the intent of footnote 20 applying to [name of product] for young children.

Docosahexaenoic acid [20)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	**-**	-	**~~[~~30~~]~~**
mg/100 kJ	**-**	-	**~~[7.9]~~ 7.2**

[20)] If docosahexaenoic acid (22:6n-3) is added to follow-up formula, a minimum level of ~~[~~**13 mg/100 kcal (3.1 mg/ 100 kJ)**~~]~~ should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as docosahexaenoic acid. 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 of their local population.

Recommendation 3:

New Zealand supports recommendation 3 - the adoption of a minimum level for fat of 3.5 g /100 kcal (0.84 g/100 kJ) for [name of product] for young children as this level accommodates formulations based on reduced fat cow's milk.

Recommendation 4:

New Zealand strongly supports limiting the addition of sugars (mono- and disaccharides) to [name of product] for young children due to their metabolic and sweetening effects and has considered how this is best achieved. New Zealand notes that both recommendations 4 and 5 address restrictions on carbohydrates, but considers that the maximum level of total available carbohydrates and the limits for the type of carbohydrates should be considered independently. New Zealand acknowledges that the maximum level of available carbohydrates has a small impact on the total amount of sugars (mono- and disaccharides) because their limit is considered to be set as a percentage of total available carbohydrates. However, New Zealand does not consider it to be significant in the context of the progressively diversified diet of young children.

New Zealand notes that recommendation 4 relates to all available carbohydrates and as such can support a maximum level of either 12.5 g/100 kcal or 14 g/100 kcal for [name of product] for young children. New Zealand notes that flexibility on the maximum level of available carbohydrates would allow for formulations that are closer to the lower limits of both total fat and protein.

Recommendation 5:

New Zealand supports the recommendation to establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates and considers that mono- and disaccharides are well-defined and it is not necessary to list their potential sources. In addition, New Zealand considers that the sentence in footnote 4 that "Sucrose and/or fructose should not be added, unless needed as a carbohydrate source" could be deleted as their addition would need to fit within the limit set for mono- and disaccharides.

New Zealand does not consider further restrictions on sweet tasting carbohydrates necessary and considers they would be difficult to define and not practical to enforce. New Zealand welcomes discussion on the need to consider other non-carbohydrate ingredients which might be added with the purpose of imparting a sweet taste but is not aware of such ingredients being used in the manufacturing of these products at this point in time.

Carbohydrates

Available cabohydrates[4)]

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	-	[12.5] **or [14.0]**	-
g/100 kJ	-	[3.0] **or [3.3]**	-

[4)] Lactose should be the preferred carbohydrate in [name of product] based on milk protein. ~~Sugars, other than lactose [or other carbohydrates contributing to the sweet taste of [name of product] should not exceed [10%] or [20%] of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.~~

~~[~~Mono- and disaccharides~~]~~, other than lactose**,** should not exceed 20% of available carbohydrate. **~~[Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.]~~** ~~Sucrose and/or fructose~~ **~~[and/or other carbohydrates contributing to the sweet taste of [name of product]]~~** ~~should not be added, unless needed as a carbohydrate source.~~ **~~[Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]~~**

Clean copy:

[4)] Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, should not exceed 20% of available carbohydrate.

Recommendation 6:

New Zealand agrees with recommendation 6 that the percentage limit for mono- and disaccharides is converted to an absolute amount based on the energy density (g/ 100 kcal and g/ 100 kJ) of product for young children once a decision is made on the maximum level of available carbohydrates.

Recommendation 7:

New Zealand agrees with recommendation 7 that a calcium-to-phosphorus ratio for [name of product] for young children not be included in the Standard, given that the diverse diet of a young child contains various sources of phosphorus.

Recommendation 8:

New Zealand agrees with the mandatory addition of vitamin D to [name of product] for young children and the minimum and maximum levels proposed in the Draft Standard.

Vitamin D			
Unit	**Minimum**	**Maximum**	**GUL**
µg[9)] /100 kcal	[1.5]	[4.5]	-
µg[9)] /100 kJ	[0.36]	[1.08]	-
[9)] Calciferol. 1 µg calciferol = 40 IU vitamin D.			

PREAMBLE

Recommendation 9:

New Zealand supports the approach proposed by the Codex Secretariat, WHO and the Chairs of the eWG, that being to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA resolutions, noting this approach to the Preamble would replace the need to list or reference these documents and resolutions within different sections of the Standard itself (including the Scope).

If an infant is not breastfed, the only alternative to breast-milk for an infant under the age of 6 months is infant formula. From 6 months on, when complementary feeding is being progressively introduced, follow-up formula for older infants can be used as either a replacement for infant formula or a substitute for breast-milk. Therefore, New Zealand is of the view that both infant formula and follow-up formula for older infants should be considered to be breast-milk substitutes.

New Zealand is however of the view that [name of product] for young children should not be considered a breast-milk substitute. It is necessary to consider the role that this product has in the diets of young children as well as national infant and young child feeding guidelines. In many countries, including New Zealand, whole cows' milk is recommended as a suitable drink from 12 months of age. Therefore, product for young children, given as an alternative to cows' milk would be considered a liquid part of the increasingly diversified diet from the age of 12 months on.

New Zealand notes and supports the comments in the 2016 Consultation Paper that product for young children is often used as a substitute, alternative or replacement for cows' milk, and agrees with the following guiding principles used to determine the mandatory essential composition of [name of product] for young children and agreed to at CCNFSDU38. Evidence to support:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate; and/or
2. contribution of adequate amounts of *key nutrients from milk*, and *if appropriate breast-milk*, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety,

The proposed composition of [name of product] for young children consequently differs substantially from infant formula and follow-up formula for older infants making it inappropriate to be considered a breast-milk substitute, and to do so, could create confusion amongst consumers. The proposed composition of [name of product] for young children requires only 13 nutrients, while the Infant Formula Standard and the proposed composition of follow-up formula for older infants both require 32 nutrients. For this reason, [name of product] for young children is not a breast-milk substitute and should not be represented as such.

With respect to the Preamble statement, New Zealand could support reference to the WHO International Code of Marketing of Breast-milk Substitutes (1981) and the Global Strategy for Infant and Young Child Feeding noting that not all parts of these documents may be relevant for the two product categories, or relevant to the national context. By way of example, some aspects of the Global Strategy are not consistent with national public health policy in New Zealand. New Zealand's *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2)* which are prepared by the New Zealand Ministry of Health (available at www.health.govt.nz) state that:

> *Homemade formula (that is, formula not prepared commercially) is not recommended because of the risks associated with inadequate composition and unsafe preparation. The concerns are that such formula will not meet nutritional requirements, will contain harmful levels of some nutrients, may include inappropriate ingredients and may be contaminated (for example, with bacteria that cause food-borne illness).*

This advice differs to that presented in the Global Strategy which states that:

> *For infants who do not receive breast milk, feeding with a suitable breast-milk substitute – for example an infant formula prepared in accordance with applicable Codex Alimentarius standards, or a home-prepared formula with micronutrient supplements - ….*

New Zealand therefore agrees to the Preamble statement proposed and has selected our preferred wording from that presented in square brackets as presented below:

*The Codex Alimentarius Commission acknowledges the need to [**protect and support** ~~**recognize**~~] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [~~**necessary** /~~ **appropriate**~~]~~, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [**as appropriate**,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / **supported**] by member states [**may also**] provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

As mentioned above, New Zealand notes that not all parts of the Global Strategy or the WHO Code may be relevant for each of the respective product categories proposed to be covered within this Standard, or relevant to our national context. For this reason, New Zealand supports the use of 'as appropriate' within the second paragraph and 'may also' within the same paragraph. New Zealand is giving further consideration to the terminology 'endorsed' vs 'supported'.

SCOPE AND LABELLING – OLDER INFANTS (6-12 MONTHS)

Recommendation 10:

New Zealand supports the statement proposed for Section 1.1 of the Scope for follow-up formula for older infants.

1.1	This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

Recommendation 11:

New Zealand supports the statement proposed for Section 1.2 of the Scope for follow-up formula for older infants with the exception of the reference to 'analytical'. New Zealand is of the view that the analytical requirements should sit outside the Follow-up Formula Standard and that the section on the Methods of Analysis and Sampling should refer to the relevant provisions within Codex Standard 234-1999: *Recommended Methods of Analysis,* as is the approach taken in Section 10 of the Infant Formula Standard.

1.2	This section of the Standard contains compositional, quality, safety, **[and]** [labelling ~~and analytical~~] requirements for Follow-up Formula for Older Infants.

Recommendation 12:

New Zealand supports the statement proposed for Section 1.3 of the Scope for follow-up formula for older infants. We acknowledge that 'shall' is consistent with the terminology used in the labelling section of the standard and therefore this is our preferred wording.

1.3	Only products that comply with the criteria laid down in the provisions of this section of this

Standard **[~~should /~~ shall]** be presented as~~]~~ Follow-up Formula for Older Infants.

Recommendation 13:

New Zealand agrees that a reference to any WHO documents and WHA resolutions should sit within the Preamble for the Standard rather than in the individual Scope sections. New Zealand also supports the recommendation of the Codex Secretariat and WHO and the proposed wording as presented in Section 5.3 of the Agenda Paper, noting our preferences for the wording options contained within the square brackets as presented under Recommendation 9. Based on this preference, New Zealand therefore agrees to the proposal to delete provision 1.4 within the Scope for follow-up formula for older infants as this provision becomes redundant if contained within the Preamble.

Recommendation 14:

New Zealand supports the proposed introductory paragraph to the Labelling Section for follow-up formula for older infants.

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

Recommendation 15:

New Zealand agrees that any discussion on nutrition claims in relation to NRVs for infants and young children should not delay the progress of reviewing the Follow-up Formula Standard. New Zealand also agrees that a decision on the need to revisit nutrition claims should NRVs be established for older infants, and the purpose of these NRVs within the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985), should form part of the ToR for a NRV working group (including the need to consider whether any labelling provisions within Codex standards for foods for infants and young children need to be revisited if NRVs are adopted by Codex).

Noting that the Committee cannot foresee the outcome of any work on NRVs for this age group should it proceed, New Zealand agrees that the status quo for nutrition (and health) claims, that is; that the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation, should remain.

Recommendation 16:

New Zealand supports recommendation 16 which includes the addition of 'or regional' within provision 9.1.2. Our preferred option for provision 9.1.4 is OPTION 1, and we support the use of 'shall' in preference to 'may' within provision 9.1.5.

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be *Follow-up Formula for Older Infants* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national ~~[~~or regional~~]~~ usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4 OPTION 1: Split provision 9.1.4 into two:

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be

labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

OR

~~OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3~~

9.1.5 A product which contains neither milk nor any milk derivative **[**shall**]** **[**~~may~~**]** be labelled "contains no milk or milk products" or an equivalent phrase.

Recommendation 17:

New Zealand notes that in the 1st Consultation Paper, the Chairs proposed that provisions 9.2.1 and 9.2.2 (relating to the List of Ingredients) of the Infant Formula Standard be adopted for Follow-up Formula for Older Infants. There was almost full support from the eWG for adopting the List of Ingredient provisions within the Infant Formula Standard for follow-up formula for older infants. We do note however that within provision 9.2.2 of the 1st and 2nd Consultation Papers, the phrase; 'In addition, appropriate class names for these ingredients and additives may be included on the label' was omitted from the Chairs proposal and this was an oversight. We have therefore included it below (see text in bold) and recommend its addition.

9.2 List of Ingredients

9.2.1 A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate class names for these ingredients and additives may be included on the label.** ~~[~~Food additives may also optionally declare the INS number~~]~~.

Recommendation 18:

New Zealand supports the proposed drafting text presented for Section 9.3 – Declaration of Nutritive Value for follow-up formula for older infants.

9.3 Declaration of Nutritive Value

The declaration of nutrition information ~~[~~for follow-up formula for older infants~~]~~ shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

Recommendation 19:

New Zealand supports the proposal contained within Recommendation 19, that is to modify Section 9.4 – Date Marking and Storage Instructions for follow-up formula for older infants (as necessary) and adopt the changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017, noting that this text is going to the Commission for adoption. These changes are presented below:

9.4 Date Marking and Storage Instructions

9.4.1[(i)]The ***"Best Before Date" or "Best Quality Before Date"*** ~~date of minimum durability (preceded by the words "best before")~~ shall be declared by the day, month and year ~~in uncoded numerical sequence~~ except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] ~~will suffice~~. ~~The month may be indicated by letters in those countries where such use will not confuse the consumer.~~ [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only

numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

[ii] In the case of products requiring a declaration of month and year only, **[~~and the shelf-life of the product is valid to the end of a given year,~~**] the **[date shall be introduced by the words "Best before end <insert date>; or "Best Quality Before end <insert date>. [**~~expression "end (stated year)" may be used as an alternative.~~**]**

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated ~~if~~ [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

Recommendation 20:

New Zealand supports the proposed drafting text presented for Section 9.5 – Information for Use for follow-up for older infants, including acceptance of the text in square brackets and deletion of the text with strikethrough. We therefore agree to the proposed rewording of provisions 9.5.1, 9.5.2 and 9.5.6 as presented.

9.5 Information for Use

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [~~Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.~~] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [~~product~~] remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

[~~[~~9.5.6 The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, ~~[is not to be used as a sole source of nutrition]~~ and that older infants should receive complementary foods in addition to the product.~~]~~]

Recommendation 21:

New Zealand supports an approach to 'Additional Labelling Requirements' for follow-up formula for older infants that is not more stringent than what is required on the label of infant formula. For that reason, we do not support inclusion of provision 9.6.2.5.

We therefore support provision 9.6.1, including the deletion of d), and 9.6.3. With respect to provision 9.6.2, we support the proposed changes including those presented for 9.6.2.1, 9.6.2.2, 9.6.2.3 and 9.6.2.4. We do not support the inclusion of 9.6.2.5.

In relation to 9.6.4, New Zealand is of the view that not all of the text proposed within the square brackets is necessary. It is our view that adequate labelling provisions regarding age and the intended consumer are already proposed and we do not believe that the statement *'…in particular as to the text, images and colours used'* adds any value or further guidance in this regard.

9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous

and easily readable message which includes the following points:

~~[~~a) the words "important notice" or their equivalent;~~]~~

b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

~~[~~c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.~~]~~

~~**[d) the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.]**~~

~~[~~9.6.2 The label shall have no pictures of infants and women nor any other picture[,] ~~or~~ text[,] ~~which idealizes the use of follow up formula. The label shall have no pictures images, text~~ or ~~other~~ representation that might:
9.6.2.1 idealize the used of follow-up formula for older infants;
9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);
9.6.2.3 recommend or promote bottle feeding;
9.6.2.4 undermine ~~or discourage~~ breastfeeding, ~~that makes a comparison to breast-milk,~~ or suggest~~s~~ that the product is ~~nearly~~ equivalent to or superior to breast-milk;
~~**9.6.2.5** convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.~~]

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. ~~**[In addition, the product should not be compared to breast-milk].**~~

~~[9.6.4]~~ Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them~~~~, in particular as to the text, images and colours used~~**.]**

SCOPE AND LABELLING – YOUNG CHILDREN (12-36 MONTHS)

Recommendation 22:

New Zealand supports the statement proposed for Section 1.1 of the Scope [name of product] for young children.

1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

Recommendation 23:

New Zealand supports the statement proposed for Section 1.2 of the Scope for [name of product] for young children with the exception of the reference to 'analytical'. New Zealand is of the view that the analytical requirements should sit outside the Follow-up Formula Standard and that the section on the Methods of Analysis and Sampling should refer to the relevant provisions within Codex Standard 234-1999: *Recommended Methods of Analysis,* as is the approach taken in Section 10 of the Infant Formula Standard.

1.2 This section of the Standard contains compositional, quality, safety, **[and]** ~~[~~labelling ~~and analytical]~~ requirements for [name of product] for young children.

Recommendation 24:

New Zealand supports the statement proposed for Section 1.3 of the Scope for [name of product] for young children. We acknowledge that 'shall' is consistent with the terminology used in the labelling section of the standard and therefore this is our preferred wording.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard ~~[**should /**~~ **shall]** be presented as~~]~~ [name of product] for young children.

Recommendation 25:

New Zealand agrees that a reference to WHO documents and WHA resolutions should sit within the Preamble for the Standard rather than in the individual Scope sections (see our comments under Recommendation 9). New Zealand supports the recommendation of the Codex Secretariat, WHO and the

Chairs of the eWG and the proposed wording as presented in Section 5.3 of the Agenda Paper, noting our preferences for the wording options contained within the square brackets. Based on this preference, New Zealand therefore agrees to the proposal to delete provision 1.4 within the Scope for [name of product] for young children as this provision becomes redundant if contained within the Preamble.

Recommendation 26:

New Zealand supports the proposed introductory paragraph to the Labelling Section for [name of product] for young children.

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to [name of product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

Recommendation 27:

New Zealand agrees that CCNFSDU should note the preference of the eWG for revisiting nutrition claims on [name of product] for young children should NRVs be established and adopted by Codex for this age group.

Further to this, New Zealand agrees that any discussion on nutrition claims in relation to NRVs for infants and young children should not delay the progress of reviewing the Follow-up Formula Standard. New Zealand also agrees that a decision on the need to revisit nutrition claims should NRVs be established for young children, and the purpose of these NRVs within the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985), should for part of the ToR for a NRV working group (including the need to consider whether any labelling provisions within Codex standards for foods for infants and young children need to be revisited if NRVs are adopted by Codex).

Noting that the Committee cannot foresee the outcome of any work on NRVs for this age group should it proceed, New Zealand agrees that the status quo for nutrition (and health) claims, that is; that the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation, should remain.

Recommendation 28:

New Zealand supports recommendation 28 which includes the addition of 'or regional' within provision 9.1.2. Our preferred option for provision 9.1.4 is OPTION 1, and we support the used of 'shall' in preference to 'may' within provision 9.1.5.

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be *[Name of Product] for Young Children* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national **[**or regional**]** usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4 OPTION 1: Split provision 9.1.4 into two:

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be

labelled '[Name of Product] for Young Children based on [name of animal] milk [protein]'.

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled '[Name of Product] for Young Children based on [name of plant] [protein]'.

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

OR

~~OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3~~

9.1.5 A product which contains neither milk nor any milk derivative **[**shall**]** **[**~~may~~**]** be labelled "contains no milk or milk products" or an equivalent phrase.

Recommendation 29:

New Zealand notes that in the 1st Consultation Paper, the Chairs proposed that provisions 9.2.1 and 9.2.2 (relating to the List of Ingredients) of the Infant Formula Standard be adopted for [name of product] for young children. There was almost full support from the eWG for adopting the List of Ingredient provisions within the Infant Formula Standard for [name of product] for young children. We do note however that provision 9.2.2 seems to have omitted from the Chairs proposal, the phrase; 'In addition, appropriate class names for these ingredients and additives may be included on the label' and this was an oversight. We have included this text (as presented in bold) and recommend its addition.

9.2 List of Ingredients

9.2.1 A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate class names for these ingredients and additives may be included on the label.** ~~[~~Food additives may also optionally declare the INS number~~]~~.

Recommendation 30:

New Zealand supports the proposed drafting text presented for Section 9.3 – Declaration of Nutritive Value for [name of product] for young children.

9.3 Declaration of Nutritive Value

The declaration of nutrition information ~~[~~for [name of product] for young children~~]~~ shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per ~~[~~serving size and/or per~~]~~ 100 kilocalories (or per 100 kilojoules) is permitted.

Recommendation 31:

New Zealand supports the proposal contained within Recommendation 31, that is to modify Section 9.4 – Date Marking and Storage Instructions for [name of product] for young children (as necessary) and adopt the changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017, noting that this text is going to the Commission for adoption. These changes are presented below:

9.4 Date Marking and Storage Instructions

9.4.1[(i)]The ***"Best Before Date" or "Best Quality Before Date"*** ~~date of minimum durability (preceded by the words "best before")~~ shall be declared by the day, month and year ~~in uncoded numerical sequence~~ except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] ~~will suffice~~. ~~The month may be indicated by letters in those countries where such use will not confuse the consumer.~~ [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

[ii]In the case of products requiring a declaration of month and year only, **[~~and the shelf-life~~**

~~**of the product is valid to the end of a given year,**~~] the **[date shall be introduced by the words "Best before end <insert date>; or "Best Quality Before end <insert date>. [**~~expression "end (stated year)" may be used as an alternative.~~**]**

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated ~~if~~ [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

Recommendation 32:

New Zealand supports the proposed modified wording presented within provision 9.5.1 and 9.5.2. We also agree with the deletion of the text within provision 9.5.3 as this is best included and covered within Section 9.6 of the Standard. New Zealand is also of the view that instructions illustrating the method of preparation are important, but for [name of product] for young children these need not be graphic. We have therefore included a modification to 9.5.3. Further to this, we suggest that provision 9.5.4 should be deleted as a warning on 'health hazards' is not appropriate for this product which is not considered to be nutritionally necessary in the diets of young children, and which would be consumed in addition to other general purpose foods. Furthermore, we consider that key issues regarding safety are covered within provision 9.6.2 and do not need to be repeated. If this provision was to be retained, there is a redundant 'and' which should be deleted.

9.5 Information for use

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [~~Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.~~] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula [~~product~~]~~ remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear ~~graphic~~ instructions **[(which may be graphic)]** illustrating the method of preparation of the product. [~~Pictures of feeding bottles are not permitted on labels of (name of product) for young children.~~]

~~**9.5.4 [**The directions should be accompanied by a warning **[**and**]** about the health hazards of inappropriate preparation, storage and use**].**~~

9.5.~~5~~[4] Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

[~~9.5.6~~[5] The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] [~~balanced~~] diet.]

Recommendation 33:

New Zealand supports provision 9.6.1, including the prohibition on images of feeding bottles on [name of product] for young children. New Zealand is of the view that not all of the text proposed within the square brackets of provision 9.6.2 is necessary. It is our view that adequate labelling provisions regarding age and the intended consumer are already proposed and we do not believe that the statement *'…in particular as to the text, images and colours used'* adds any value or further guidance in this regard.

9.6 Additional Labelling Requirements

[~~9.6.1~~ The label of [name of product] for young children shall have no image, text or representation [~~,~~including pictures of feeding bottles,~~]~~ that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.~~]~~

[~~9.6.2~~] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes[, and to enable consumers to make a clear

distinction between them, ~~in particular as to the text, images and colours used~~].

DEFINITIONS

Recommendation 34:

New Zealand's preference is for the definition of follow-up formula for older infants that we supported in our response to the second consultation paper. That being:

Follow-up formula for older infants means a product specially manufactured for use as a liquid part of the diet for older infants, either as a breast milk substitute or a replacement for infant formula when complementary feeding is introduced.

New Zealand would however be prepared to compromise based on the findings of the eWG, and if the definition presented in the Agenda Paper has the majority support of the Plenary. The definition would therefore read:

Follow-up formula for older infants means a product, specially manufactured for use as a liquid part of ~~[~~a progressively ~~/~~ diversified~~]~~ diet for older infants when complementary feeding is introduced.

Recommendation 35:

At CCNFSDU38, the Committee considered evidence to support:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate; and/or
2. contribution of adequate amounts of *key nutrients from milk*, and *if appropriate breast-milk*, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety,

to be the guiding principles used to determine the mandatory essential composition of [name of product] for young children.

New Zealand therefore supports a definition for [name of product] for young children that reflects these principles, i.e. that [name of product] for young children is a product which can be used for situations of nutritional inadequacy (principle 1) and/or as an alternative to cows' milk (principle 2) . New Zealand's preferred definition for [name of product] for young children is therefore:

[Name of product] for young children means a product specially ~~**[formulated and]**~~ manufactured for use as a liquid part of the **[progressively] [**diversified~~]~~ diet of young children **[in order to contribute to the[ir] nutritional needs ~~of young children] [~~ [or] when [their] nutrient intakes may not be adequate to meet nutritional requirements]**.

Clean copy:
[Name of product] for young children means a product specially manufactured for use as a liquid part of the progressively diversified diet of young children in order to contribute to their nutritional needs or when their nutrient intakes may not be adequate to meet nutritional requirements.

NAME OF PRODUCTS

Recommendation 36:

New Zealand agrees that the name ***Follow-up Formula for Older Infants*** should be adopted as the name of product for the 6 – 12 month age group.

Recommendation 37:

New Zealand supports the name ***Formulated drink for young children*** for product for the 12 – 36 months age group.

References

Ministry of Health. 2008. Food and Nutrition Guidelines for Health Infants and Toddlers (Aged 0-2): A background paper (4th Ed) – Partially Revised December 2012. Wellington: Ministry of Health.

FAO. 2011. Dietary Protein Quality Evaluation in Human Nutrition. Report of an FAO Expert Consultation. FAO Food and Nutrition Paper 92. Food and Agriculture Organization of the United Nations. Rome.

RUSSIA

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

1.5 Protein

1.5.1 Minimum protein level in follow-up formula for older infants

Comment on Recommendation 1:

Russian Federation retains its position, expressed in earlier consultation paper (2016), that 1.8 g /100 kcal is the minimum adequate level of protein, needed for healthy growth and development.

But for the purpose of compromise, and taking into account footnote 6), which requires, that "Follow-up formula based on non-hydrolysed milk protein containing [less than 1.8 g] protein/100 kcal [(0.43 g/100 kJ)] …… should be clinically evaluated by a competent national and/or regional authority", Russian Federation supports the proposed wording of Recommendation 1.

Comment on Recommendation 2 - 3:

Russian Federation supports theese recommendations.

Comment on Recommendation 4:

Russian Federation is disagree with the recommendation to establish a maximum level for available carbohydrates of 12.5 g/100 kcal (3.0 g/100 kJ) and confirms previous position to establish a maximum level of available carbohydrates at 14 g/100 kcal. This is adequate to nutrient requirements for young children and allows (Name of product) for Young Children to be less prescriptive and more flexible in composition.

Comment on Recommendation 5:

Russian Federation supports a maximum level of added sugars (other than lactose) of 20% of available carbohydrates (which is about 10% total energy). This is in line with the WHO recommendations (WHO, 2015).

However Russian Federation considers, that wording "contributing to sweet taste" is vague, can be interpreted in a different ways and proposes to delete last two sentences of the footnote.

Comment on Recommendation 6:

Russian Federation supports this recommendation, with the deletion of the text "and other carbohydrates contributing to the sweet taste".

Comment on Recommendation 7 - 8:

Russian Federation supports these recommendations.

Comment on Recommendation 9:

Russian Federation agrees in general with the above text of Recommendation 9, but considers inclusion of the following text " Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context" to be premature, as the Codex Alimentarius Commission (CAC41) is expected to discuss the interrelation of WHO policies and Codex mandate and the final decision whether to include this text or not would be better to make after CAC41.

Comment on Recommendation 10:

Russian Federation supports this recommendation.

Comment on Recommendation 11:

Russian Federation supports this statement in section 1.2, but would like to note, the redundancy of analytical requirements, as essentially they are related to composition, quality and safety parameters.

Comment on Recommendation 12:

Russian Federation supports this recommendation**.**

Comment on Recommendation 13:

Russian Federation does not completely support this recommendation as considers inclusion of the following text " include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper" to be premature, as the Codex Alimentarius Commission

(CAC41) is expected to discuss the interrelation of WHO policies and Codex mandate and the final decision whether to include this text or not would be better to make based on the outcome of the discussion at CAC41.

Comment on Recommendation 14:

The Russian Federation agrees with above recommendation. However, we consider that nutrition claims , which inform consumer about ingredients (“lactose free”, “gluten free”, “contains no milk ingredients”) and nutrition value of product help the consumers and caregivers to make informed choice.

Restrictions on communications of follow-up formula for older infants to parents/caregivers potentially can to lead to unhealthy food choices for older infants.

Comment on Recommendation 15:

Russian Federation is not agree with this recommendation and suggests that a reference to NRVs for older infants should be made in the section 5.3.1.

Comment on Recommendation 16:

Russian Federation supports the recommendation for provisions 9.1.1, 9.1.2and 9.1.3. In provision 9.1.4 Russian Federation supports Option1 as it is more clear and precise.

Comment on Recommendation 17 - 19:

Russian Federation supports these recommendations.

Comment on Recommendation 20:

Russian Federation considers, that in section 9.5.6 the wording “[is not to be used as a sole source of nutrition]” should be retained, as it is a distinctive feature of Follow on formula vs Infant Formula and parents/caregivers are better to be reminded about it.

Comment on Recommendation 21:

Russian Federation supports this recommendation in general, however considers, that the following wordings are redundant and should be deleted:

9.6.2.2: the sentence “(including references to milestones and stages)”

- 9.6.2.5: the entire section

Comment on Recommendation 22:

Russian Federation supports this recommendation.

Comment on Recommendation 23:

Russian Federation supports this statement in section 1.2, but would like to note, the redundancy of analytical requirements, as essentially they are related to composition, quality and safety parameters

Comment on Recommendation 24:

Russian Federation supports this recommendation.

Comment on Recommendation 25:

Russian Federation does not completely support this recommendation as considers inclusion of the following text “ include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper” to be premature, as the Codex Alimentarius Commission (CAC41) is expected to discuss the interrelation of WHO policies and Codex mandate and the final decision whether to include this text or not would be better to make based on the outcome of the discussion at CAC41.

Comment on Recommendation 26:

The Russian Federation agrees with above recommendation. However, we consider that nutrition claims , which inform consumer about ingredients (“lactose free”, “gluten free”, “contains no milk ingredients”) and nutrition value of product help the consumers and caregivers to make informed choice.

Restrictions on communications of follow-up formula for older infants to parents/caregivers potentially can to lead to unhealthy food choices for older infants.

Comment on Recommendation 27:

Russian Federation does not agree with this recommendation and suggests that a reference to NRVs for young children should be made in the section 6.3.1.

Comment on Recommendation 28:

Russian Federation supports the recommendation for provisions 9.1.1, 9.1.2 and 9.1.3. In provision 9.1.4 Russian Federation supports Option1 as it is more clear and precise.

Comment on Recommendation 29:

Russian Federation supports this recommendation.

Comment on Recommendations 30 - 32:

Russian Federation agrees with these recommendation.

Comment on Recommendation 33:

Russian Federation in general is agree with this recommendation and proposes to add to the paragraph 9.6.1. the following wording: "The products covered by this standard are not breast-milk substitutes and shall not be presented as such."

Russian Federation would nevertheless request the CCNFSDU to reinstate the provision that (name of product) for young children is not a breastmilk substitute (or, if it is preferred to avoid use of this term, not a substitute for human milk) in provisions detailed in 9.6 of Section B of the revised standard.

The point, that [name of product] for young children are not breastmilk substitutes was discussed and supported by eWG and should be reflected in final document. Indeed, (name of product) for young children is never developed to satisfy all nutritional needs of young children and always is used as part of the diversified diet.

Comment on Recommendation 34:

Russian Federation supports this recommendation.

Comment on Recommendation 35:

Russian Federation considers, that the part of sentence "when nutrient intakes may not be adequate to meet nutritional requirements" should be deleted, as it can bring to the conclusion, that non-adequacy of diet should be verified, while clear and concise criteria may not be available.

Comment on Recommendation 36:

Russian Federation is agree with this recommendation.

Comment on Recommendation 37:

Russian Federation supports both variants of names.

SENEGAL

RECOMMENDATION NO	POSITION/RESPONSE	COMMENTS
1	No comment	
2	No comment	
3	Can support	We would have liked the minimum fat level to be 4g/100kcal for the reasons given in the paper pertaining to the fact that reduced fat cow's milk is not recommended for children during the first three years of life and that higher fat is needed to support child growth and development.
4	Support	Because the young children needs are higher than those for infants
5	Support	
6	No comment	
7	No comment	
8	No comment	
9	Do not support	We strongly disagree with this proposal. We believe that this standard shall explicitly referenced to relevant WHO documents and WHA resolutions in all of its section including preamble and scope.

10	Support	
11	Support	
12	Support with use of SHALL	We would support the text provided that the word **SHALL** in the square brackets is accepted. It is our opinion that 'shall' is imperative and makes the text emphatic and unambiguous.
13	Do not support	We cannot support this recommendation unless the Preamble text includes explicit reference to WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9. If not included in the Preamble then provision 1.4 must not be deleted and must refer to WHA 39.28, WHA 63.23 and WHA 69.9.
14	Support	
15	Support	
16	Support with option 2 for 9.1.4	We support option 2 in 9.1.4 to delete provision 9.1.4 as it is covered by 9.1.3
17	Support	
18	Support	
19	Support	
20	Support if "Ready to use" is deleted	The word 'ready to use' should be deleted since it is vague and this standard is addressed to specific products.
21	Support	WHA 69.9 adopted in 2016 and its associated Guidance is clear that the product is a breastmilk substitute and as such must comply with the International Code of Marketing of Breast-milk Substitutes, it is thus essential that the additional labelling requirements (9.6) must encompass all elements of the Code and be aligned with the equivalent text in the Infant Formula Standard.
22	Support	
23	Support	
24	Support with use of SHALL	We would support the text provided that the word **SHALL** and in the square brackets is accepted. It is our opinion that 'shall' is imperative and makes the text emphatic and unambiguous.
25	Does not support	We cannot support this recommendation unless the Preamble text includes explicit reference to WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9. If not included in the Preamble then provision 1.4 must not be deleted and must refer to WHA 39.28, WHA 63.23 and WHA 69.9.
26	Support	
27	Support	
28	Support with option 2 for 9.1.4	We support option 2 in 9.1.4 to delete provision 9.1.4 as it is covered by 9.1.3
29	Support	
30	Support	
31	Support	
32	Support if "Ready to use" is deleted	The word 'ready to use' should be deleted since it is vague and this standard is addressed to specific products.
33	Can support but…	We strongly believe that the text in 9.6 Additional Labelling Requirements must thus be consistent with the associated text in 9.6 for Follow-up Formula for Older Infants.
34	Does not support	We strongly oppose the proposed text regarding the product definition for Follow-Up Formula for older infants and believes the definition must explicitly states that these products are breastmilk substitutes according to WHA resolution 69.9.

35	Does not support	These products function as breastmilk substitutes because their consumption displaces rather than complements the intake of breastmilk. It would be totally unacceptable for this standard not to ensure that this definition is in line with WHA resolution 69.9 that includes guidance that explicitly states that these products are breastmilk substitutes.
36	Support	
37	Does not support	There is no need to include any adjective to the name of the product. The use of any of the proposed adjective 'formulated' could be interpreted as indicating a benefit and we strongly oppose this and believe it to be not only potentially misleading but also in contravention of the International Code of Marketing of Breast-milk Substitutes that prohibits any promotion and idealisation of these products.

SWITZERLAND

Recommendation 1

1.5 Protein

Switzerland would like to propose that the wording of footnote 6 be amended as follows:

~~[~~[6)] Follow-up formula based on non-hydrolysed milk protein containing [less than 1.8 g] protein/100 kcal [(0.43 g/100 kJ)] and follow-up formula based on hydrolysed protein containing less than ~~[~~2.25 g protein/100 kcal~~]~~ (0.54 g/100 kJ) [**should be clinically tested by the food business operator in the context of its auto-control to ensure its safety and suitability**].

Recommendation 4

2.5.2 Maximum level of available carbohydrate

Switzerland supports setting the maximum available carbohydrate level **no higher than 10 g per 100 kcal** as it is the only option that approximates to the carbohydrate composition of whole cow's milk (6.9 g/100 kcal) or breastmilk (10 g/100 kcal).

Recommendation 5

2.6 Sugar other than lactose, and other sweet tasting carbohydrates

Switzerland's preferred option for the percentage limits that should be applied:

10% of available carbohydrate applicable to sugars other than lactose, and other carbohydrates contributing to the sweet taste.

Switzerland is of the opinion that the preferred carbohydrate formulation for [name of the product] for young children, besides lactose, should be long-chain carbohydrates:

[Name of the product] for young children **should not be sweeter than whole cow's milk or breastmilk**.

Switzerland prefers this option because it is the best choice in countering several health issues that are rapidly increasing worldwide, caused in part by excessive ingestion of sweetened food products.

These health issues include overweight, obesity and diabetes, not forgetting the negative impact on tooth health (dental caries).

Reducing sugar content in early childhood is one way to reduce accustomisation to an excessively sweet taste. Accustomisation to a strongly sweet taste could increase the risk of overweight or obesity.

Recommendation 9

3 Preamble

Switzerland is of the opinion that the preamble should contain a reference to the WHA69.9 resolution:

Ending Inappropriate Promotion of Foods for Infants and Young Children.

Amended preamble with preferred wording presented in square brackets:

*The Codex Alimentarius Commission acknowledges the need to [**protect and support ~~/recognize~~**] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [**necessary ~~/ appropriate~~**], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [**~~as~~ if appropriate**,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981)[**,**] ~~and~~ the Global Strategy for Infant and Young Child Feeding [**and the resolution WHA69.9 on Ending Inappropriate Promotion of Foods for Infants and Young Children**]. Relevant WHO guidelines and policies as well as [**other**] relevant World Health Assembly (WHA) resolutions that have been [**endorsed ~~/ supported~~**] by member states ~~[**may also**]~~ provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Recommendation 12

5.2.3 Scope – Section 1.3

For section **1.3**, Switzerland prefers the following terminology:

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [**~~should /~~ shall**] be presented as Follow-up Formula for Older Infants.

Recommendation 16

5.4 Labelling – Name of product

Switzerland prefers OPTION 1 and would like to propose a supplementary provision 9.1.4(c), for Follow-up Formula for Older Infants based on a mixture of milk and plant proteins, as this is already endorsed by Swiss and several other national legislations:

9.1.4(c) If [name of animal] milk and [name of plant] are the sources of proteins[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk and [name of plant] [proteins]'.

Recommendation 24

6.2.3 Scope – Section 1.3

For section 1.3, Switzerland prefers the following terminology:

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [**~~should /~~ shall**] be presented as~~]~~ [name of product] for young children.

Recommendation 28

6.4 Labelling – Name of the Product (9.1)

Switzerland prefers OPTION 1. As for Follow-up Formula for Older Infants, Switzerland proposes a provision 9.1.4(c) for [Name of Product] for Young Children as follows:

9.1.4(c) If [name of animal] milk and [name of plant] are the sources of proteins[*], the product may be labelled '[Name of Product] for Young Children based on [name of animal] milk and [name of plant] [proteins]'.

Recommendation 37

8.2 Name of product for young children

Switzerland agrees with the Chair's proposal and prefers the first name:

Formulated drink for young children.

UNITED STATES OF AMERICA

SPECIFIC COMMENTS:

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS

(6-12 MONTHS)

Recommendation 1:

The United States previously supported the minimum level of 1.8 g/100 kcals for protein because the data is insufficient to support a reduction in protein to 1.6 g/100 kcals as an international standard. However, the United States could accept 1.6 g/100 kcals for protein as long as there are sufficient and suitable high quality protein sources available in the diversified diet for the 6-12-month-old infant to provide adequate intake of protein as indicated in our edits to footnote 6 below.

a) Protein 2), 3), 4)

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.6]5),6)	3.0	-
g/100 kJ	[0.38]5),6)	0.72	-

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

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 of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); 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.

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

5) The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' **[or non-goats']** milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of **[**2.25 g/100 kcal (0.5**4** g/100 kJ)**]** applies.

[[6) Follow-up formula based on non-hydrolysed milk protein containing **[less than 1.8 g]** protein/100 kcal **[(0.43 g/100 kJ)]** and follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] **(0.54 g/100 kJ) shall** ~~should~~ be clinically evaluated by a competent national and/or regional authority. Consideration to the protein sources in the diversified diet should be used to determine if the level of protein in the formula is suitable and available for the 6-12 month old infant].

Recommendation 2:

The United States continues to support the principle that minimum level of DHA should be set as proposed in Recommendation 2 in footnote 20. The rationale for proposing a fixed minimum level was to avoid the level of DHA/EPA from becoming too low when levels of fatty acids are reduced. We agree with the findings from the EU (EFSA 2014) and consider a fixed level of DHA at a higher minimum be considered. We consider the range supported by the eWG of 16-20 mg/100 kcals as an appropriate alternative because it is unlikely that infants 6-12 months of age will consume other sources of DHA in their diversified diet. We prefer to take the midpoint of the percentage of fatty acid range (0.4%) and the midpoint of the fat range 5.2g/100kcal to set the minimum level which rounds to 20mg/100kcal.

We also note that because many members indicated that this type of information was needed to support regulations, we continue to support this approach and the level of 30 mg/100 kcal as the guidance upper limit (GUL). It is reasonable to provide levels of optional ingredients that have been shown to have a level needed to provide for its physiological effects. Please consider the edits to footnote 20.

Docosahexanoic acid 20)

Unit	Minimum	Maximum	GUL
mg/100 kcal	**-**	-	**[30]**
mg/100 kJ	**-**	-	**[7.9]**

20) If docosahexanoic acid (22:6n-3) is added to follow-up formula, a minimum level of [20 mg/100 kcal (4.75 mg/ 100 kJ)] should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as docosahexaenoic acid. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of long chain polyunsaturated fatty acids (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 of their local population based on the suitability and availability of food sources of DHA in the diversified diet.

ESSENTIAL COMPOSITION OF [NAME OF PRODUCT] FOR YOUNG CHILDREN (12-36 MONTHS)

Recommendation 3:

The United States could support Recommendation 3 to establish a minimum level for fat of 3.5 g /100 kcal (0.84 g/100 kJ). A minimum level of 3.5 g/100 kcal would be required to accommodate reduced fat cows' milk. However, we note that consideration should be given to a higher amount of fat (40% of calories) depending on the macronutrient contribution of the product. The United States notes that 3.5.g fat/100 kcal is not feasible if the protein minimum is set at 1.6 g/100 kcal and the carbohydrate maximum is set at 12.5 g/100 kcal or 14 g/100 kcal.

Recommendation 4:

The United States finds Recommendation 4 problematic. In considering a maximum level for carbohydrate we find that when minimum levels of protein and fat are used, the level of carbohydrate needed to achieve 100 kcals is greater than 14 g/100 kcal calculated by difference. In this case, using these minimums would require the carbohydrate level to be approximately 15.5 g/ 100 kcal would be needed).

We also note that setting a maximum carbohydrate level to 12.5 g/100kcal (3.0 g/100 kJ) limits formulation flexibility. Thus, it may not be practical to use the minimum for protein and fat and maximum for carbohydrate regardless of whether the carbohydrate level is 12.5 or 14 g/100 kcal. For example, if the minimum protein is 1.6 g/ 100 kcal and the maximum for carbohydrate is 12.5 g/100 kcal, then the level for fat will need to be 4.8 g/100kcal by difference. We suggest the Committee consider how the modeling demonstrated how the level of one macronutrient affects the others and affects the feasibility of macronutrient levels.

In addition, we consider it important to remember that not all products will be milk based and consideration should be made regarding the sources of carbohydrate in plant based products.

Recommendation 5:

The United States supports the concerns expressed in Recommendation 5 regarding overly sweetened products. We note that the maximum level of available carbohydrate could prevent the product from tasting overly sweet depending upon the carbohydrate source. Products that contain only lactose will be less sweet than products containing other sugars. We support footnote 4 as stated below regarding carbohydrates in milk based products with further discussion.

Carbohydrates

Available cabohydrates[4])

Unit	Minimum	Maximum	GUL
g/100 kcal	-	[12.5]	-
g/100 kJ	-	[3.0]	-

4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Sugars, other than lactose [or other carbohydrates contributing to the sweet taste] of [name of product] should not exceed [20%] of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

Recommendation 6:

The United States supports the consideration of Recommendation 6 as stated below. However, we note the importance of having further discussion about how an absolute amount will be determined (eg based on energy density versus on total carbohydrate) and if having an absolute value could result in product limitations.

That CCNFSDU agree that the percentage limit for sugars [and other carbohydrates contributing to the sweet taste] is converted to an absolute amount based on the energy density (g/ 100 kcal and g/ 100 kJ) of product for young children once a decision is made on the maximum level of available carbohydrates.

Recommendation 7:

The United States does not support Recommendation 7 in which no calcium-to-phosphorous ratio is included for [name of product] for young children. The United States notes that the addition of calcium to a product suggests that consideration for the inclusion of other minerals such as phosphorus should be assessed in order to ensure proper nutrient balance in the particular product. We support the calcium to phosphorus minimum and maximum ratios because imbalance in calcium and phosphorus levels can lead to poor bone mineralization and other issues. Other potential nutrient interactions with other minerals (e.g. magnesium, zinc, and iron) and relationships would also need to be considered so that the nutrients are bioavailable to the young child from the product's matrix.

We suggest the following ratios be considered:

Ratio calcium/ phosphorus

Min	Max
1:1	2:1

Recommendation 8:

The United States supports the mandatory addition of Vitamin D, as it has been identified as an at-risk nutrient of global concern. We support the minimum levels level of 1.5 ug/100 kcal and maximum level of 4.5 ug/100 kcal because it is required for calcium absorption and is also involved in maintaining bone mineral homeostasis and regulation of renal calcium excretion.

Vitamin D

Unit	Minimum	Maximum	GUL
µg[9]) /100 kcal	**[1.5]**	**[4.5]**	**-**
µg[9]) /100 kJ	**[0.36]**	**[1.08]**	**-**

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

Recommendation 9:

The United States recognizes the chair's difficult challenge in drafting a preamble to the standard. We have considerable concerns with the preamble in its current form. In our view, it is attempting to address numerous issues, that while important, go beyond the scope of the Codex Mandate and what is needed for this standard. In particular, the United States cannot support general references to unspecified WHO/WHA texts and the sentence: "Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed/supported] by member states [may also] provide guidance to countries in this context" should be removed.

We have a recommendation that may facilitate moving this work forward. Specifically, the United States suggests we delay the task of drafting an appropriate preamble until after the technical work on the standard is completed. At that point we can better determine how to address part A and part B of the standard in relation to proper child feeding. We would ask the Committee to consider this recommendation.

We wish to note that currently Section A of the standard is more aligned with the Infant Formula Standard (CODEX STAN 72-1981) while Section B of the standard has a nutritional profile which contributes to balancing the complementary foods part of the diet of a young child.

Recommendation 10:

The United States supports Recommendation 10 for Section 1.1 and suggests including the age range to avoid confusion between products as edited below:

1.1 This section of the Standard applies to Follow-up Formula for Older Infants [(6-12 months old)], as defined in Section 2.1, in liquid or powdered form.

SCOPE AND LABELLING OLDER INFANTS (6-12 MONTHS)

Recommendation 11:

The United States supports Recommendation 11 and considers it important to recognize that there are two categories of products intended for two different populations. We support the wording as stated below for Section 1.2 as well as the removal of the brackets from labelling and analytical:

1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.

Recommendation 12:

United States supports Recommendation 12 that states the following and suggests that "shall" be considered rather than "should".

Only products that comply with the criteria laid down in the provisions of this section of this Standard **[~~should /~~ shall]** be presented as] Follow-up Formula for Older Infants.

Recommendation 13:

The United States recommends we discuss Recommendation 13 once the nutritional composition of follow up formula for older infants is finalized.

Recommendation 14:

The United States supports inclusion of an introductory paragraph to the Labelling Section for follow-up formula for older infants (Section A), as follows:

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to follow-up formula (FUF) for older infants.

Recommendation 15:

The United States supports not waiting for NRVs to be set and suggests the Guidelines for Nutrition Labelling be referenced to avoid any labelling provisions in the Standard needing to be revisited should the Guidelines be updated.

Recommendation 16:

The United States supports Recommendation 16 that states the labelling requirements for FUF for older infants using Option 2, removal of the square brackets under 9.1.2, and renumbering as follows:

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national ~~[~~or regional~~]~~ usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4 A product which contains neither milk nor any milk derivative ~~[~~shall~~]~~ ~~[may~~] be labelled

"contains no milk or milk products" or an equivalent phrase.

Recommendation 17:

The United States supports the proposed text in Recommendation 17 for the provisions in 9.2 through 9.2.2 as stated below and consider the phrase "including optional ingredients" as redundant and should be deleted.

9.2 List of Ingredients

9.2.1 A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food

additives. ~~[~~Food additives may also optionally declare the INS number~~]~~.

Recommendation 18:

The United States supports the proposed text in Recommendation 18 for the provisions in 9.3 and the removal of the square brackets under 9.3 and use "as well as." This wording will provide clarity in labeling so that information is provided on an "as sold" and "as prepared" basis.

9.3 Declaration of Nutritive Value

The declaration of nutrition information ~~[~~for follow-up formula for older infants~~]~~ shall contain

the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number

of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared

according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100

kilojoules) is permitted.

Recommendation 19:

The United States supports Recommendation 19 to maintain consistency with the text and outcomes of CCFL44 in October 2017.

Recommendation 20:

The United States supports Recommendation 20 for section 9.5 on the information for use and supports the removal of square brackets from 9.5.1 with some additional edits for clarity. We consider the addition of the word "potable" important in 9.5.1 to ensure that the water source is not only microbiologically safe but is also untainted and free of any other hazards with revised wording suggested below. We also support the removal of square brackets from 9.5.6 with the deletion of "sole source nutrition" phrase.

9.5 Information for Use

9.5.1 ~~[~~Ready to use~~]~~ products in liquid form may be used directly. Concentrated liquid products ~~[~~and powdered products], must be prepared with [*potable water]* and according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be

discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of

the product.

9.5.4 The directions should be accompanied by a warning about the health hazards of

inappropriate preparation, storage and use.

9.5.5 Adequate directions regarding the storage of the product after the container has been

opened, shall appear on the label.

~~[~~9.5.6 The label of follow-up formula for older infants shall include a statement that the

product shall not be introduced before 6 months of age, [~~is not to be used as a sole source of~~

~~nutrition]~~ and that older infants should receive complementary foods in addition to the product.]

Recommendation 21:

The United States supports the objectives of Recommendation 21 for additional labelling requirements for older infants which are addressing a number of important issues. We suggest modification of Recommendation 21 for the older infants as suggested below with the removal of the square brackets. This recommendation also reflects our comments to Recommendation 33.

9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding. The label of [name of product] for older infant shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of [name of product] for older infant. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.

[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between

infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in to the text, images and colours used.

SCOPE AND LABELLING – YOUNG CHILDREN (12-36 MONTHS)

Recommendation 22:

The United States supports Recommendation 22 as stated below for Section 1.1 and suggests including the age range (12-36 months) to avoid confusion between products as edited below:

1.1 This section of the Standard applies to [name of product] for young children [(12-36 months old)], as defined in Section 2.1, in liquid or powdered form.

Recommendation 23:

The United States supports removal of the square brackets from labelling and analytical as stated below in Section 1.2.

1.2 This section of the Standard contains compositional, quality, safety, [labelling and

analytical~~]~~ requirements for [name of product] for young children.

Recommendation 24:

The United States supports Recommendation 24 that states the following and suggests that "shall" be considered rather than "should".

1.3 Only products that comply with the criteria laid down in the provisions of this section

of this Standard ~~[should /~~ shall] be presented as~~]~~ [name of product] for young children.

Recommendation 25:

The United States recommends we discuss Recommendation 25 once the nutritional composition of follow up formula for younger children is finalized.

Recommendation 26:

The United States supports inclusion of an introductory paragraph to the Labelling Section for [name of product] for young children (Section B) with the following edits:

The requirements of the Codex *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to [name of product] for young children.

Recommendation 27:

The United States supports not waiting for NRVs to be set and suggests the Guidelines for Nutrition Labelling be referenced to avoid any labelling provisions in the Standard needing to be revisited should the Guidelines be updated.

Recommendation 28:

The United States supports Recommendation 28 that states the labelling requirements for [name of product] for young children using option 2, use of "shall", and renumbering as follows:

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be *[Name of Product] for Young Children* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4 A product which contains neither milk nor any milk derivative ~~[~~shall~~]~~ ~~[may]~~ be labelled

"contains no milk or milk products" or an equivalent phrase.

Recommendation 29:

The United States supports the proposed text in Recommendation 29 for the provisions in 9.2 through 9.2.2 as stated below and consider the phrase "including optional ingredients" as redundant and should be deleted. We also support the removal of brackets from 9.2.2

9.2 List of Ingredients

9.2.1 A complete list of ingredients [~~including optional ingredients~~] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food

additives. ~~[~~Food additives may also optionally declare the INS number].

Recommendation 30:

The United States supports the proposed text in Recommendation 30 for the provisions in 9.3 and the removal of the square brackets under 9.3 and use "as well as." This wording will provide clarity in labeling so that information is provided on an "as sold" and "as prepared" basis.

9.3 Declaration of Nutritive Value

The declaration of nutrition information [for [name of product] for young children] shall contain

the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as] ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and

any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres

of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared

according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per ~~[~~serving size and/or per~~]~~ 100

kilocalories (or kilojoules) is permitted.

Recommendation 31:

The United States supports Recommendation 31 to maintain consistency with the text and outcomes of CCFL44 in October 2017.

Recommendation 32:

The United States supports Recommendation 32 for section 9.5 on the information for use and supports the removal of square brackets from 9.5.1 with some additional edits for clarity. We consider the addition of the word "potable" important in 9.5.1 to ensure that the water source is not only microbiologically safe but is also untainted and free of any other hazards with revised wording suggested below. We also support the removal of square brackets from 9.5.6 with the deletion of "sole source nutrition" phrase.

9.5 Information for use

9.5.1 [Ready to use] products in liquid form may be used directly. Concentrated liquid products ~~[~~and powdered products~~]~~, must be prepared with [*potable]* and according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula [~~product~~]~~ remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of

the product. ~~[~~Pictures of feeding bottles are not permitted on labels of (name of product) for young children.~~]~~

9.5.4 ~~[~~The directions should be accompanied by a warning and about the health hazards of

inappropriate preparation, storage and use~~]~~.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

[9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a ~~[~~diversified~~]~~ ~~[~~balanced~~]~~ diet.~~]~~

Recommendation 33:

The United States supports Recommendation 33 as reflected below with the suggested edits for 9.6.2 and the removal of the square brackets suggested by the Chair of the eWG in 9.6 .1 and 9.6.2. We note that although the compositional profile for the product for young children is not yet completed, the composition of the product is different from breast milk and should not be used as a breast milk replacement.

9.6 Additional Labelling Requirements

[9.6.1] The label of [name of product] for young children shall have no image, text or

representation [, including pictures of feeding bottles,] that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.]

[9.6.2] [The products covered by this standard are nutritionally different from breast milk and are not to be used as breast-milk substitutes and shall not be presented as such.] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes [, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colors used].

Recommendation 34:

The United States supports the proposal that the definition for follow-up formula for older infants with the removal of the square brackets and the forward slash between the words, "progressively" and "diversified" within the square brackets as stated below. We also suggest changing "when" to "as" to reflect the process of this transitioning diet:

Follow-up formula for older infants means a product, specially manufactured for use as a liquid

part of [a progressively ~~/~~ diversified] diet for older infants ~~when~~ [as] complementary feeding is introduced.

Recommendation 35:

The United States supports the proposal that the definition of (name of product) for young children be edited and recommends the following wording to best reflect the use of this product:

[Name of product] for young children means a product specially ~~[~~formulated and~~]~~ ~~–~~manufactured for use as a liquid part of the progressively ~~–~~diversified diet and that specifically contributes to the nutrient needs of young children.

Recommendation 36:

The United States supports the name ***Follow-up Formula for Older Infants*** *as the name of the product for the 6 – 12-month-old age group (older infants).*

Recommendation 37:

The United States supports ***"Formulated drink for young children"*** *and suggests that the age range be included (ages 12-36 months).*

EU SPECIALITY FOOD INGREDIENTS

Recommendation 1 on minimum protein level

EU Specialty Food Ingredients supports a minimum protein level of 1.8 g/100 kcal with a footnote supporting a lower protein level up to 1.6 g/100 kcal if evaluated and endorsed by national competent authorities as agreed at last year's CCNFSDU Session.

Protein is a key nutrient for adequate growth and development during infancy and childhood.

Scientific substantiation for the nutritional suitability of a lower protein level has been demonstrated for European infants (EFSA 2017). The overall conclusion of EFSA's assessment was that the use of follow-up formula for older infants with a protein content of at least 1.6 g/100 kcal from milk protein (cows' or goats') that otherwise comply with EU legislation is safe and suitable for infants living in Europe with access to

complementary foods of a sufficient quality. However, this scientific substantiation has not been demonstrated at global level, and thus at present is not appropriate to be incorporated into a global standard. Keeping the minimum at 1.8 g/100 kcal with a footnote is therefore seen as an appropriate way.

References:

EFSA 2017. EFSA NDA Panel. Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal. EFSA Journal 2017;15(5):4781, https://doi.org/10.2903/j.efsa.2017.4781

Recommendation 2 on optional addition of DHA

EU Specialty Food Ingredients would like to support the following wording for the table and note linked to DHA for FUF for older infants

Docosahexaenoic acid (DHA) note)			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	- (note)	**-** (note)	**~~[30]~~ 50**
mg/100 kJ	-	**-**	**~~[7.9]~~ 12**
note) If docosahexaenoic acid (22:6n-3)(i.e. DHA) added to follow-up formula, a minimum level of **~~13 mg/100 kcal (3.1 mg/100 kJ)~~ 20 mg/100 kcal (4.8 mg/100 kJ)** should be reached and arachidonic acid (20:4 n-6) (i.e. ARA) content should reach at least the same concentrations as docosahexaenoic acid. The content of eicosapentaenoic acid (20:5 n-3), which **~~can~~ may** occur in sources of n-3 LC-PUFA added as a source of DHA**,** should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions**, ~~as~~ if substantiated ~~appropriate~~ to address** ~~for~~ the nutritional needs of the national/regional populations			

EU Specialty Food Ingredients would like to make the following comments in support of our position:

- Principles regarding the addition of optional ingredients:

  Codex Alimentarius endorsed the following principles for the addition of optional ingredients in follow-up formula for older infants "*3.2.2 When any of these ingredients or substances are being added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk".*

  When considering the addition of optional ingredients, and for this purpose the addition of DHA, the selected minimum DHA level should be sufficient to achieve the intended effect, considering levels in human milk. Hence it is critical to clearly define the intended beneficial effect as this will consequently determine the minimum DHA levels required.

- Defining the minimum level enabling to achieve the intended effect:

  Several globally recognized expert authorities (e.g., FAO, EFSA) have reviewed and concluded that a minimum level is required to achieve intended beneficial effects related to the addition of n-3 LC-PUFA, and in particular DHA.

  Therefore, EU Specialty Food Ingredients supports the wording recognizing the need for a minimum level to be established when DHA is added as suggested by the Chairs of the eWG on follow-up formula and published in CX/NFSDU 17/39/4.

  However, we consider that the level of 13 mg/100 kcal is insufficient to meet this specific requirement for older infants, and we believe this suggestion (i) is contrary to the minimum level of 20 mg/100 kcal, which was the point of departure for further discussions which had been agreed by at the last CCNFSDU 38th session (see page 57 of English version of CCNFSDU38 report *in* REP17/NFSDU Appendix IV) and (ii) does not reflect properly any consensus found in this year electronic working group where many countries supported a value of 20 mg/100 Kcal (e.g. USA, the 28 member countries of the European Union).

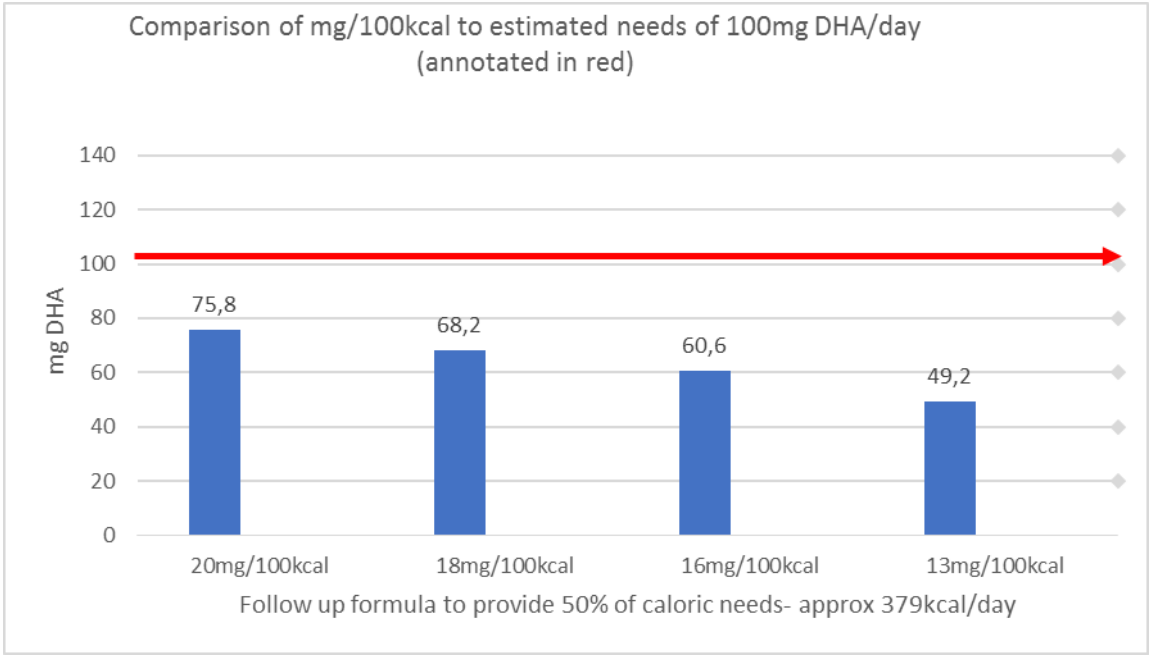
  In the light of all the above elements, EU Specialty Food Ingredients supports a minimum level of 20 mg/100 kcal when DHA is being added as optional ingredient.

- Scientific substantiation in support of a minimum DHA level at 20 mg/100 kcal:

  The following scientific findings are to be considered in support of a minimum level of 20 mg/100 kcal:

- The daily requirement for DHA has been set at approximately 100 mg by different key scientific recognized bodies (EFSA (2013), FAO (2010)).
- Older infants consume about 500 mL of breastmilk or an equal volume of follow-up formula, which corresponds to approximately 325 to 379 kcal/day.
- Establishing the minimum level of DHA at 20 mg/100 kcal would result in an approximate daily intake of 65 to 76 mg DHA. Although this daily intake is lower than the established daily intake by scientific authorities it is more meaningful as compared to the daily intake if the level would be only 13 mg/100 kcal (42-49 mg). See below figure 1, which illustrates the contribution made towards the daily requirement of 100mg DHA per day by a FUF providing 13, 16, 18 or 20 mg DHA/100 kcal.

Figure 1.



- A level of 20 mg/100 kcal is similar to the recommended level established by EFSA (EFSA 2014) and endorsed by the EC for follow-on formula marketed in the European Union (EC 2016) .
- A level of 20 mg/100 kcal is among the range of levels of DHA found in human milk (Brenna, 2007).
- A level of 20mg/100 kcal provides up to 75% of the daily DHA requirements. This level of addition in part addresses a nutrient gap identified in many countries, where intake of complementary foods such as fish, meats, and eggs, the primary sources of dietary DHA and ARA are extremely limited in the diets of older infants (Forsyth 2016).

Consequently, a level of 20mg/100 kcal complies with the Codex Alimentarius principles for optional ingredients, namely providing levels that are providing an intended benefit considering levels found in human milk.

- <u>Setting the Guidance Upper Level (GUL) for DHA:</u>

Regarding the setting of the GUL, we support 50 mg/100 kcal based on the highest observed DHA concentration in breastmilk (around 1% DHA total fat) which appears to be safe for older infants (Brenna et al, 2007). Depending on the fat content of FUF, 1% DHA equates to between 44 mg/100 kcal and 60 mg/100 kcal.

Based on global human milk data it is scientifically relevant to consider that a level of 50 mg/100 kcal is adequate to be set as a guidance upper level for DHA in follow-up formula.

- <u>Mandatory addition of ARA when DHA is added:</u>

EU Specialty Food Ingredients supports the mandatory addition of ARA when DHA based on the following scientific data:

- ARA is an essential component of all cell membranes. It has a key structural and functional role in the central nervous system and is a metabolic requirement for all cells as a precursor of eicosanoids which modulate a variety of biological processes particularly those relating to cerebral, cardiovascular and immune function (Calder 2015). The amount of ARA incorporated into the

developing brain during infancy exceeds the deposition of DHA (Martinez (1992), Makrides (1994)). Although humans can synthesize ARA to some extent from linoleic acid, infants-fed formula without pre-formed ARA tend to develop lower ARA levels in blood plasma and erythrocytes than breast-fed infants who receive both DHA and ARA (Koletzko (2007), Carlson (2001)).

- Infant and follow-up formula providing both DHA and ARA have been evaluated in numerous controlled trials, the use of formula with up to 1% DHA and no ARA would be a novel concept that has not been systematically evaluated nor clinical assessed for its effects, suitability and safety (Koletzko, 2015).
- As a consequence, it is considered appropriate, as highlighted by several expert authorities (e.g., US FDA) to include the addition of ARA when DHA is being added to follow-up formulas.

- Potential presence of EPA:

  EU Specialty Food Ingredients would like to emphasize that with respect to the potential presence of EPA when DHA is being added, some sources of DHA are substantially higher in EPA (e.g. fish oil) as compared to other sources (e.g. algal sources). Therefore, we propose to slightly amend the proposed wording and replace “can occur” by “may occur”.

- Enabling and substantiating national/regional deviations:

  Regarding the potential national/regional deviations, even if we believe a Codex standard should limit these deviations to serve its intended purpose, we understand that there may be some regions where the intake from complementary foods is higher due to the consumption of fish. We therefore propose to modify the last sentence on the DHA paragraph to enable national/regional nutritional needs when scientifically substantiated.

References

Brenna J.T., Varamini B., Jensen R.G., Diersen-Schade D.A., Boettcher J.A., Arterburn L. M. (2007). Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. American Journal of Clinical Nutrition, 85:1457-64.

Carlson S.E. (2001) Docosahexaenoic acid and arachidonic acid in infant development. Seminars in Neonatology, 6: 437–449.

Calder P. (2005) Functional Roles of Fatty Acids and their effects on human health. Journal of Parenteral and Enteral Nutrition, 39(S):18S-32S.

EFSA 2013, Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408, 103 pp. doi:10.2903/j.efsa.2013.3408

EFSA (2014a) Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 12(7):3760.

EFSA (2014b) Scientific Opinion on the substantiation of a health claim related to DHA and contribution to normal brain development pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 12(10):3840.

EC (2016) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

Food and Agricultural Organization of the United Nations (FAO), 2010. FAO Food and Nutrition Paper 91.

Forsyth S., Gautier S., Salem Jr. N. (2016) Estimated dietary intakes of arachidonic acid and docosahexaenoic acid in infants and young children living in developing countries. Annals of Nutrition and Metabolism, 69:64-74.

Koletzko B., Sauerwald T., Demmelmair H., Herzog M., von Schenck U., Bohles H., et al. (2007) Dietary long-chain polyunsaturated fatty acid supplementation in infants with phenylketonuria: a randomized controlled trial. Journal of Inherited Metabolic Disorders, 30: 326–332.

Koletzko B., Carlson S.E., van Goudoever J.B. (2015) Should infant formula provide both omega-3 DHA and omega-6 arachidonic acid? Annals of Nutrition and Metabolism, 66:137–138.

Martinez M. (1992) Tissue levels of polyunsaturated fatty acids during early human development. Journal of Pediatrics, 120: S129–S138.2

Makrides M., Neumann M.A., Byard R.W., Simmer K. & Gibson R.A. (1994) Fatty acid composition of brain, retina, and erythrocytes in breast- and formula-fed infants. American Journal of Clinical Nutrition, 60: 189–194.

EU Specialty Food Ingredients comment on the Section 2.5. Carbohydrates in the Essential composition of [Name of product] for young children

The provisions and wordings proposed in Section B, [Name of the product] for young children, paragraph (c) on carbohydrates of the current draft standard are acceptable to us and that we therefore have no comments on the related recommendations 4 and 5 (pages 17 respectively 22 of CX/NFSDU/17/39/4)

However, we noted a more editorial, but nevertheless essential, mistake in the background section of chapter 2.5. on carbohydrates, related to the definition of dietary fibre (see page 16 of CX/NFSDU/17/39/4). The **footnote clarifying that the inclusion of carbohydrates from DP 3-9 is upon decision of national authorities is missing**. This footnote is an integral part of the dietary fibre definition laid down in the Codex Guidelines on Nutrition Labelling (CAC/GL-2-1985), and reads as follows: "*Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities*".

We therefore recommend adding this footnote to the definition for dietary fibre established under section 2.5.1. of the CCNFSDU agenda paper (page 16) in order to avoid confusion and to align with the definition laid down in the relevant Codex Guidelines on Nutrition Labelling.

Recommendation 8 on vitamin D minimum and maximum in the Essential composition of [Name of product] for young children

EU Specialty Food Ingredients supports the proposal by the eWG Chairs to define a minimum vitamin D level of 1.5 µg/100 kcal (0.36 µg/100 kJ) and a maximum vitamin D level of 4.5 µg/100 kcal (1.08 µg /100 kJ).

EU Specialty Food Ingredients supports the general agreement by the eWG participants that a vitamin D level of 1.5 µg/100 kcal should be adopted as the minimum level given the significant level of vitamin D insufficiency in older infants and young children.

Similarly, we support a higher maximum vitamin D level at 4.5 µg/100 kcal, which is in line with recommendations by the International Expert Group coordinated by the Early Nutrition Academy (Suthutvoravut et al. 2015)

Recommendation 9 on the preamble

EU Specialty Food Ingredients considers that the discussion as to the inclusion of WHO guidance and WHA resolutions are a procedural matter that are to be discussed and agreed upon by the CAC in line with the Codex Procedural Manual. As these discussions are currently ongoing at CAC, we consider it is not up to the eWG to make recommendations.

Recommendation 14 on labelling of FUF for older infants

EU Specialty Food Ingredients supports the use of nutrition claims for Follow-Up Formula for older infants. A claim such as "source of XX" is a useful information for health care professionals and parents.

Recommendation 26 on labelling of [Name of product] for young children

EU Specialty Food Ingredients supports the use of nutrition and health claims for [Name of product] for young children. As the diet of the young children is diversifying when the young children are growing, this information will be included on other products not covered by this Codex standard. This would be an unfair competition, with [Name of product] for young children specifically designed to suit the nutritional needs of this population not being able to properly communicate on the intended effect of the product.

EU Specialty Food Ingredients comments on the structure of the standard for the [name of product] for young children (essential composition and optional ingredients) in Appendix II

We believe the numbering of the paragraphs are wrong (page 87). It currently reads as below going from 3.1.1. directly to 3.2 with sub-paragraphs 3.2.1 and 3.2.2. Then paragraph 3.2. and sub-paragraphs 3.2.1. and 3.2.2. are further used on page 90 to describe the provisions for optional ingredients. Therefore, there are two paragraphs numbered 3.2. and two sub-paragraphs 3.2.1 and 3.2.2.

3 **ESSENTIAL COMPOSITION AND QUALITY FACTORS**

3.1 **Essential composition**

3.1.1 **[Name of product] for young children** 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 young children.

3.2 The nutritional safety and adequacy of [Name of Product] for young children shall be scientifically demonstrated to support growth and development of young children.

3.2.1 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (293 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

3.2.2 (Name of product) for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL), as appropriate.

a) Protein[*), **)]

Therefore, we believe the subtitles under "3.1. Essential composition" shall be modified as follows:

3.1 Essential composition

3.1.1 [Name of product] for young children 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 young children.

~~3.2~~ 3.1.2 The nutritional safety and adequacy of [Name of Product] for young children shall be scientifically demonstrated to support growth and development of young children.

~~3.2.1~~ 3.1.3 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (293 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

~~3.2.2~~ 3.1.4 [Name of product] for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL), as appropriate.

The above-mentioned suggestions have an impact on the numbering used on page 90 for the provisions of optional ingredients.

3.2 Optional Ingredients

3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.1.3 Section A are also permitted.

3.2.2 When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

We understood that the text is reflective of the fact only a narrow set of mandatory requirements is the basis of the essential composition and that additional ingredients can be added, on a voluntary basis. However, these optional additions are linked to the nutritional needs of the population. Therefore, our understanding is that the 3 paragraphs under "3.2. optional ingredients" mean the following:

3.2.1 means that other ingredients can be added to the essential composition of [name of product] for young children where their use is considered safe and suitable by national and/or regional authorities and demonstrated by generally accepted scientific evidence. This can include the optional ingredients from FUF, described in 3.2. Section A.

3.2.2 states that sufficient amounts are necessary

3.2.3 explains that the essential composition for FUF for older infants can also be used when looking at which additional nutrients can be added to YCF.

So our understanding is that the text under 3.2. SECTION B should be modified as follows:

3.2. Optional ingredients (in YCF)

3.2.1. In addition to the essential composition requirements listed under ~~3.1.3~~ 3.1 Section B (or 3.1.4 Section B), other ingredients, substances or nutrients may be added to YCF where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in ~~3.1.3~~ 3.2. Section A are also permitted.

3.2.2 When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.~~3~~ Section A (or 3.1.4. Section A)) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

Therefore, in practice, it means that for example, folic acid and manganese which are part of the essential composition of FUF for older infants could be added to [name of product] for young children.

Choline and DHA which are optional ingredients in FUF for older infants could also be added in YCF. For both choline and DHA, the scientific evidence and the recommendations from various institutions confirm their importance for children 1-3 years of age.

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S (GOED)

Recommendation 2:

GOED supports a modified version of the eWG's Recommendation 2 for Docosahexaenoic Acid (DHA) including proposals for higher guidance upper levels (GUL) and in relation to footnote 20). Please see below the proposed changes presented in underlined and strikethrough form as follows:

Docosahexaenoic acid (DHA) [20)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	**~~[30]~~ 50**
mg/100 kJ	-	-	**~~[7.9]~~ 12**

[20)] If docosahexaenoic acid (22:6n-3**; DHA**) is added to follow-up formula, a minimum level of [**~~13 mg/100 kcal (3.1 mg/100 kJ)~~ 20 mg/100 kcal (4.8 mg/100 kJ)**] should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as docosahexaenoic acid. The content of eicosapentaenoic acid (20:5 n-3), which ~~can~~ **may** occur in sources of **n-3** LC-PUFA, **added as a source of DHA,** should not exceed the content of **DHA**~~docosahexaenoic acid~~. Competent national and/or regional authorities may deviate from the above conditions, ~~as appropriate for~~ **if substantiated to address** the nutritional needs of their **national/regional** ~~local~~ population**s.**

Rationale:

The following comments support GOED's proposed modifications:

- Principles regarding the addition of optional ingredients

  Codex Alimentarius (CX/NFSDU 17/39/4[2]) endorsed the following principles for the addition of optional ingredients in follow-up formula (FUF) for older infants "*3.2.2 When any of these ingredients or*

[2] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-39%252Fnf39_04e.pdf

substances are being added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk."

When considering the addition of optional ingredients (i.e. DHA), the selected minimum level should be sufficient to achieve the intended effect, considering levels in human milk; therefore, it is critical to clearly define the intended beneficial effect as this will determine the minimum DHA levels required.

- Defining the minimum level to achieve the intended effect

  When DHA is added as an optional ingredient, GOED supports a minimum level of 20 mg/100 kcal.

  Several globally recognized expert authorities (e.g., FAO, EFSA) have reviewed and concluded that a minimum level is required to achieve intended beneficial effects related to the addition of n-3 LC-PUFAs, particularly DHA; therefore, GOED supports the suggestion by the eWG chairs on FUF and published in CX/NFSDU 17/39/4 for text recognizing the need for a minimum level of DHA when it is added. However, 13 mg/100 kcal is insufficient to meet this specific requirement for older infants, and we believe this suggestion (i) is contrary to the minimum level of 20 mg/100 kcal, which was placed in [ ] at CCNFSDU38 and (ii) does not reflect a consensus from this year's electronic working group where many countries supported a value of 20 mg/100 Kcal (e.g. USA, EU28 member countries of the European Union).

- Scientific substantiation in support of a minimum DHA level at 20 mg/100 kcal

  The following support a minimum DHA level of 20 mg/100 kcal:

  - The daily requirement for DHA has been set at approximately 100 mg by different key scientific recognized bodies.
  - Older infants (> 6 months of age) consume about 500 mL/day of breastmilk or an equal volume of FUF, which corresponds to approximately 325 to 379 kcal/day.
  - Establishing the minimum level of DHA at 20 mg/100 kcal would result in an approximate daily intake of 65-76 mg DHA. While this daily intake is lower than the established daily intake of 100 mg by scientific authorities, it is more meaningful compared to the daily intake if the level would be only 13 mg/100 kcal (42-49 mg).
  - A DHA level of 20 mg/100 kcal is similar to the recommended level established by EFSA and endorsed by the EC for follow-on formula marketed in the European Union.
  - A DHA level of 20 mg/100 kcal is within the range found in human milk.
  - A DHA level of 20 mg/100 kcal provides up to 75% of the daily DHA requirements. This level of addition in part addresses a nutrient gap identified in many countries, where intake of complementary foods such as fish, meats, and eggs, the primary sources of dietary DHA, are extremely limited in the diets of older infants.

  Consequently, a level of 20 mg/100 kcal complies with the Codex Alimentarius principles for optional ingredients, namely providing levels that achieve an intended benefit, considering levels found in human milk.

- Setting the Guidance Upper Level (GUL) for DHA

  Regarding the setting of the GUL, GOED supports 50 mg/100 kcal based on the highest observed DHA concentration in breastmilk (around 1% DHA total fat) which appears to be safe for older infants.[v] Depending upon the fat content of FUF, 1% DHA equates to 44-60 mg/100 kcal.

  Based on global human milk data, it is scientifically relevant to consider that a DHA level of 50 mg/100 kcal is adequate as a GUL for DHA in FUF.

- Potential presence of Eicosapentaenoic Acid (EPA)

  With respect to the potential presence of EPA when DHA is added, some sources of DHA are substantially higher in EPA (e.g., fish oil) compared to other sources (e.g., algal sources); therefore, GOED proposes to amend slightly the proposed wording and replace "can occur" by "may occur".

- Enabling and substantiating national/regional deviations

  Regarding the potential national/regional deviations, even if we believe a Codex standard should limit these deviations to serve its intended purpose, we understand that there may be some regions where the intake from complementary foods is higher due to the consumption of fish. We therefore propose to

modify the last sentence of the DHA paragraph to enable national/regional nutritional needs when scientifically substantiated.

References

[1] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to DHA and contribution to normal brain development pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2014;12(10):3840 Available online at http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3840/pdf

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[1] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760. Available online at http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3760/epdf

[1] European Commission. Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Available online at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.025.01.0001.01.ENG

[1] Brenna J.et al. (2007). Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr 85:1457-64.

[1] Forsyth S. et al. (2016). Estimated dietary intakes of arachidonic acid and docosahexaenoic acid in infants and young children living in developing countries. Ann Nutr Metab 69:64-74.

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HELEN KELLER INTERNATIONAL (HKI)

GENERAL COMMENT: CODEX ALIMENTARIUS MUST PUT SAVING CHILDRENS LIVES FIRST

Helen Keller International would like to remind the CCNFSDU Committee of the purpose of Codex Alimentarius as written in the Procedural Manual, "*These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade.*" Codex plays a critical role in protecting optimal infant and young child feeding practices. Standards developed by Codex often serve as the basis for national legislation, and, as such, have a profound impact on infant and young child nutrition. Yet protecting both consumer health and trade can come into conflict, as is evident in the current debate regarding this agenda item, the Review of the Standard for Follow-up Formula – where trade and commercial interests are clearly taking preference over health.

Codex has the opportunity to protect breastfeeding and improve child nutrition and make a major contribution to reducing preventable child deaths. We therefore appeal that at this meeting, the matter be discussed with the focus on protecting consumer health. While the world has made tremendous progress in reducing child mortality, unless we change course, by 2030, 69 million children will die before reaching their fifth birthday – most of them from poor countries. Compared to the richest children, the poorest children are 1.9 times more likely to die before age 5. The conversation at Codex has to be focused on saving children's lives in the least developed countries and low- and middle-income countries. These countries generally lack the resources to develop their own standards and largely rely on Codex to recognise their needs and to support them. In addition, these countries, often do not have either the human or financial resources to attend Codex or be part of working groups. This means that at the CCNFSDU, the commercial interests of high income countries and the economic interests of manufacturers of follow-up formula are being made loud and clear, while the voices of low- and middle-income countries are being drowned out.

The world took a bold step towards saving children's lives at the 2016 World Health Assembly when countries adopted resolution WHA 69.9. Codex must take an equally bold step and define follow-up formula, for both the 6-12 age group and 12-36 month age group, as breastmilk substitutes.

The market for breastmilk substitutes, especially in low- and middle-income countries, is lucrative and growing-- predicted to reach USD 70 billion by 2018. CCNFSDU cannot let trade and commercial interests of the developed world and breastmilk substitute manufacturers dictate global policy, undermine breastfeeding and claim children's lives.

SPECIFIC COMMENTS

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

RECOMMENDATION 1 – PROTEIN REQUIREMENTS

Helen Keller International has no comment to make on this recommendation.

RECOMMENDATION 2 – DECOSAHEXAENOIC ACID

Helen Keller International does not support the current proposed level of 13mg/100kcal (3.1mg/kJ) as this is too low. We feel strongly that the minimum in the footnote should be 20mg/100kcal.

RECOMMENDATION 3 – MINIMUM TOTAL FAT

Helen Keller International does not support the recommendation. We support the view that the minimum fat level be 4g/100kcal for the reasons outlined in the discussion paper pertaining to the fact that reduced fat cow's milk is not recommended for children during the first three years of life and that a higher fat level is necessary to support child growth and development.

RECOMMENDATION 4 – MAXIMUM LEVEL AVAILABLE CARBOHYDRATE

Helen Keller International supports the recommendation.

RECOMMENDATION 5 – LIMIT ADDITION OF 'OTHER SWEET TASTING CARBOHYDRATES'

Although Helen Keller International argued for a lower maximum level, we can support the recommendation.

RECOMMENDATION 6 – CONVERSION OF % LIMITS TO AN ABSOLUTE AMOUNT BASED ON ENERGY DENSITY

Helen Keller International supports the recommendation.

RECMMENDATION 7 - CALCIUM TO PHOSPHORUS RATIO

Helen Keller International has no comment to make on this recommendation.

RECOMMENDATION 8 – VITAMIN D

Helen Keller International supports the recommendation.

PREAMBLE

RECOMMENDATION 9 – PROPOSED APPROACH

Helen Keller International strongly disagrees with the proposal in this recommendation. We believe it is too early to propose that the text put forward, that removes specific reference by name to the relevant WHA resolutions, represents a "workable solution" despite the overview and background information included in the document under discussion.

We draw attention to the minutes of the 38th CCNFSDU meeting that states (paragraph 106) "*There was also very broad support to include references to the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and all relevant World Health Assembly resolutions and WHO guidelines in the scope of the draft Standard. These included WHA 39.28, WHA 63.23 and WHA 69.9."*

In addition, paragraph 110 states "*The Representative of WHO supported the proposal to use the contents of the scope from the Standard for Infant Formula and formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) which include references to the International Code of the Marketing of Breast-milk Substitutes and relevant WHA resolutions, but the reference to WHA resolutions should be expanded to include recent relevant WHA resolutions, including 69.9."*

The WHO has confirmed that the above remains their position.

Further, the 2017 EWG consultation re-emphasised the above and as the current document states *"…there were more respondents supporting reference to one or more WHO/WHA documents within the Follow-up Formula Standard than there were respondents against any form of reference*."

So, while we appreciate that a way forward is being sought, we believe that this document has to be explicit in the Preamble stating appropriate documents/WHA resolutions in order to protect and promote optimal infant and young child feeding and do not consider the proposed text to be a "workable solution".

- We believe that WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9 must be referenced.
- We do not believe that there is sufficient consensus to warrant the text proposed in the current document, that excludes reference to specific WHA resolutions.
- We believe that this year's CCNFSDU meeting must open the discussion as it concluded at the 38th meeting. This view is supported by both the WHO and by UNICEF - the custodians of the rights of children.

SCOPE AND LABELLING

OLDER INFANTS (6-12 MONTHS)

RECOMMENDATION 10 – SECTION 1.1

Helen Keller International supports the recommendation.

RECOMMENDATION 11 – SECTION 1.2

Helen Keller International supports the recommendation.

RECOMMENDATION 12 – SECTION 1.3

Helen Keller International would support the text, provided that the word **SHALL** in the square brackets is accepted. It is our opinion that 'shall' is imperative and makes the text emphatic and unambiguous. The text must prohibit manufacturers being able to develop another name/category of products that they justify as bypassing the standard.

RECOMMENDATION 13 – SECTION 1.4

Helen Keller International does not support this recommendation unless the Preamble text includes explicit reference to WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9. If not included in the Preamble then provision 1.4 must not be deleted and must refer to WHA 39.28, WHA 63.23 and WHA 69.9. This view is supported by UNICEF (the custodian of the rights of children) and the WHO has confirmed that their position remains that WHA 69.9 must be referenced.

RECOMMENDATION 14 – GUIDELINES ON USE OF NUTRITION AND HEALTH CLAIMS

Helen Keller International strongly supports the recommendation.

RECOMMENDATION 15 – NRVs FOR INFANTS AND YOUNG CHILDREN

Helen Keller International supports the recommendation.

RECOMMENDATION 16 – NAME OF PRODUCT

9.1.1 Helen Keller International supports the recommendation.

9.1.2 Helen Keller International supports the recommendation allowing for regional designation.

9.1.3 Helen Keller International supports the recommendation.

9.1.4 Helen Keller International supports option 2 to delete provision 9.1.4 as it is covered by 9.1.3.

9.1.5 Helen Keller International supports the recommendation. It is our opinion that 'shall' is imperative and makes the text emphatic and unambiguous.

RECOMMENDATION 17 – LIST OF INGREDIENTS

Helen Keller International supports the recommendation.

RECOMMENDATION 18 – DECLARATION OF NUTRITIVE VALUE

Helen Keller International supports this text as we believe that it is critical to provide comprehensive information considering the vulnerability of those being fed these products.

Helen Keller International however draws the Committee's attention to the fact that we believe there is an error in 9.3 c) where the serving size option has been omitted. It is our opinion that 9.3 c) should read '*In addition, the declaration of nutrients in a) and b)* ***per serving size and/or*** *per 100 kilocalories (or per 100 kilojoules) is permitted*.'

RECOMMENDATION 19 – DATE MARKING AND STORAGE INSTRUCTIONS

Helen Keller International supports the recommendation.

RECOMMENDATION 20 – INFORMATION FOR USE

9.5.1: Delete 'ready to use'.

All other square brackets can be deleted and deleted words accepted.

RECOMMENDATION 21 – ADDITIONAL LABELLING REQUIREMENTS

WHA 69.9 adopted in 2016, and its associated Guidance, is clear that the product is a breastmilk substitute and as such must comply with the International Code of Marketing of Breast-milk Substitutes. It is thus essential that the additional labelling requirements (9.6) must encompass all elements of the Code and be aligned with the equivalent text in the Infant Formula Standard.

9.6.1 a) Helen Keller International supports the deletion of the square brackets.

9.6.1 b) Helen Keller International supports the text.

9.6.1 c) Helen Keller International supports the deletion of the square brackets.

9.6.1 d) Helen Keller International does not support the deletion of this text. We believe that it is critical that this specific category of product includes the statement "The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding" as it is necessary to ensure that users fully understand that this product is not necessary. We could however consider text that combines 9.6.1 b) and this d) and such text could read "Breast milk is best for your baby and the use of this product must not replace breastmilk and lead to cessation of continued breastfeeding."

9.6.2 Helen Keller International supports the deletion of the square brackets around the entire text.

9.6.2 Helen Keller International supports the removal of the square brackets in the initial sentence and the deletion of strikethrough text.

9.6.2 We would also like to point out an error in the opening sentence text - the words 'older infants' needs to be inserted so that the sentence reads "*The label shall have no pictures of infants, **older infants** and women nor any other…*" This text must be inserted as according to the other definitions in this standard there are 2 categories - infants and older infants and so this text must be aligned with the definitions and not permit pictures of either category of infant.

9.6.2.1 Helen Keller International supports this text.

9.6.2.2 Helen Keller International supports this text.

9.6.2.3 Helen Keller International supports this text.

9.6.2.4 Helen Keller International does not support any of the proposed deletions. The text should thus read *"undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk*;". If the reference to making a comparison to breastmilk is retained here, it can be deleted in 9.6.3.

9.6.2.5 Helen Keller International supports this text.

9.6.3 Helen Keller International can support the deletion of the strikethrough text PROVIDED that the concept of no comparisons being made to breastmilk is included in 9.6.2.4. Otherwise the strikethrough text can be retained here in 9.6.3 and be removed in 9.6.2.4.

9.6.4 Helen Keller International can support the removal of all the square brackets.

YOUNG CHILDREN (12-36 MONTHS)

RECOMMENDATION 22 – SECTION 1.1

Helen Keller International supports the recommendation.

RECOMMENDATION 23 – SECTION 1.2

Helen Keller International supports the recommendation.

RECOMMENDATION 24 - SECTION 1.3

Helen Keller International would support the text provided that the word **SHALL** and in the square brackets is accepted. It is our opinion that 'shall' is imperative and makes the text emphatic and unambiguous. The text must prohibit manufacturers being able to develop another name/category of products that they justify as bypassing the standard.

RECOMMENDATION 25 – SECTION 1.4

Helen Keller International cannot support this recommendation unless the Preamble text includes explicit reference to WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9. If not included in the Preamble then provision 1.4 must not be deleted and must refer to WHA 39.28, WHA 63.23 and WHA 69.9. This view is supported by UNICEF (the custodian of the rights of children) and WHO has confirmed that their position remains that WHA 69.9 must be references.

RECOMMENDATION 26 - INGREDIENT AND NUTRIENT DECLARATIONS/CLAIMS

Helen Keller International supports the recommendation.

RECOMMENDATION 27 – NRVS FOR INFANT AND YOUNG CHILDREN

Helen Keller International supports the recommendation.

RECOMMENDATION 28 – NAME OF PRODUCT

9.1.1 Helen Keller International supports the recommendation.

9.1.2 Helen Keller International supports the recommendation allowing for regional designation.

9.1.3 Helen Keller International supports the recommendation.

9.1.4 Helen Keller International supports option 2 to delete provision 9.1.4 as it is covered by 9.1.3.

9.1.5 Helen Keller International supports the recommendation. It is our opinion that 'shall' is imperative and makes the text emphatic and unambiguous.

RECOMMENDATION 29 – LIST OF INGREDIENTS

Helen Keller International supports the recommendation.

RECOMMENDATION 30 – DECLARATION OF NUTRITIVE VALUE

Helen Keller International supports the recommendation.

RECOMMENDATION 31 – DATE MARKING AND STORAGE INSTRUCTIONS

Helen Keller International supports the recommendation.

RECOMMENDATION 32 – INFORMATION FOR USE

9.5.1 Delete 'ready to use'. Delete all other square brackets and deleted words.

9.5.2 Delete square brackets around products.

9.5.3 Delete all deleted words.

9.5.4 Delete square brackets.

9.5.5 Delete square brackets around entire text and delete square brackets around 'diversified'.

RECOMMENDATION 33 – ADDITIONAL LABELLING REQUIREMENTS

Helen Keller International does not believe that there is sufficient consensus [21 for option 1 (even if 1 is a CMO) and 16 for option 2] to only present the text of option 1 from the EWG. It is clear from the comments received during the EWG consultations that low- and middle-income countries have expressed a concern about the inappropriate use of these products. HKI believes that this text must be comprehensive so as to support optimal infant and young child feeding and the globally accepted recommendation of continued breastfeeding up to 2 years or beyond.

We strongly believe that the text in 9.6 Additional Labelling Requirements must thus be consistent with the associated text in 9.6 for Follow-up Formula for Older Infants. We thus believe Option 2 should still be included in the discussion as there is no consensus on this item.

DEFINITIONS

RECOMMENDATION 34

HKI strongly opposes the proposed text regarding the product definition for Follow-Up Formula for older infants and believes the definition must include that these products are breastmilk substitutes.

We draw attention to the fact that in the first EWG '*the EWG was split in its view on whether the definition should reference what follow-up formula for older infants is replacing in the diet...*' During the second round, 15 members selected the proposal that included a reference to being a breastmilk substitute and 16 and 1 CMO (representing 28 countries) supported removing the reference to breastmilk substitutes.

While we recognise the significant change in views from the first EWG consultation to the second EWG consultation, we believe that there is not sufficient consensus not to re-open the discussion for alternative text adapted from the second consultation that reads "Follow up formula for older infants means a product, specifically manufactured for use as a substitute for breastmilk in the progressively diversified diet of older infants when complementary feeding is introduced."

HKI believes that without opening the text for further discussion, low- and middle- income countries where the burden of malnutrition exists and who rely heavily on Codex text, are put at a disadvantage and is contrary to the mandate of Codex.

The function of this product is to replace the breastmilk that the young child should be consuming. The global recommendation for optimal infant and young child feeding is that a child should continue to receive breastmilk to 2 years and beyond. Breastmilk should serve as the liquid component of these young children's diets. These products thus de facto function as breastmilk substitutes because their consumption displaces rather than complements the intake of breastmilk. It is therefore critical that in the interests of fulfilling its mandate of providing consumer health protection, these products are clearly defined as being breastmilk substitutes. It would be totally unacceptable for this standard not to ensure that this definition is in line with WHA resolution 69.9 that includes guidance that explicitly states these products are breastmilk substitutes.

RECOMMENDATION 35

Helen Keller International cannot support the proposed definition. HKI feels strongly that the proposed definition cannot be accepted and that the discussion must be re-opened as there is not consensus on the proposed definition – 28 of the 37 responses. Not re-opening this definition for discussion puts low- and middle- income countries, where the burden of malnutrition exists and who rely heavily on Codex text, at a disadvantage and is contrary to the mandate of Codex.

The function of this product is to replace the breastmilk that the young child should be consuming. The global recommendation for optimal infant and young child feeding is that a child should continue to receive breastmilk to 2 years and beyond. Breastmilk should still be included in the diet of children 12-36 months and any other milk product will displace breastmilk. These products de facto function as breastmilk substitutes because their consumption displaces rather than complements the intake of breastmilk.

It is therefore critical that in the interests of fulfilling its mandate of providing consumer health protection, these products are clearly defined as being breastmilk substitutes. It would be totally unacceptable for this standard not to ensure that this definition is in line with WHA resolution 69.9 that includes guidance that explicitly states that these products are breastmilk substitutes.

RECOMMENDATION 36

Helen Keller International supports the recommendation.

RECOMMENDATION 37

Helen Keller International does not support either of the options presented and believes these products should either be called 'Drink for young children' or 'Young child drink'.

As it has globally been accepted that these products are not necessary, HKI continues to strongly believe that the name given must be neutral and contain no implied benefit/claim. There is no need to include any adjective to the name of the product. The use of any of the proposed adjective 'formulated' could be interpreted as indicating a benefit and we strongly oppose this and believe it to be not only potentially misleading but also in contravention of the International Code of Marketing of Breast-milk Substitutes that prohibits any promotion and idealisation of these products. HKI feels strongly that the name 'Drink for young children' or 'Young child drink' would be the best description and thus be the appropriate name of the product.

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)

IACFO supports the comments made by IBFAN.

INTERNATIONAL BABY FOOD ACTION NETWORK (IBFAN)

GENERAL COMMENTS

1. To simplify the implementation of regulations at national level and avoid confusion**, IBFAN is proposing that products targeting babies 6-36 months be included in the standard for Infant Formula and Formula for Special Medical Purposes intended for Infants Codex Stan 72-1981.** This one standard can easily accommodate all breastmilk substitutes. The could be four sections to differentiate products as follows:

   Section A: Infant formula (birth onwards or 0-12month and beyond)

   Section B: Formulas for Special Medical Purposes

   Section C: Follow-up formula for older infants (6 months onwards)

   Section D: [Name of the Product] for Young Children (12-36 months)

2. IBFAN agrees to an over-arching preamble that specifically references all the relevant WHO documents, the *Global Strategy on Infant and Young Child Feeding*, *the International Code of Marketing of Breastmilk Substitutes* and relevant WHA resolutions, including the WHA resolution 69.9 (2016) and its

accompanying *WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children*. It is important that these documents and Resolutions are also embedded in each section of the Standard. This is necessary to ensure that Member States apply these safeguards into national regulations that will protect older infants and young children from needless and inappropriate use of these products, consistent with national nutrition and health policies.

3. IBFAN does not agree with the deletion of provision 1.4 in the Scope. The scope must remind Regulatory Authorities of the safeguards contained in the over-arching Preamble WHO recommendations must underpin the marketing and labelling of each product category. The safeguarding of the health of older infants and young children through the protection of breastfeeding and optimal complementary feeding as recommended to two years or beyond must be prioritized.
4. The preamble should clearly state that these products are not necessary as endorsed by Member States in WHA Resolution 39.28 and that Member States are free to refuse their entry.
5. Appropriate nutrient levels for these products are difficult to determine because they are dependent on the amount of breastmilk consumed, the availability, quality and quantity of complementary foods consumed and cultural food practices. Infant formula that is appropriate for the first 6 months of life can continue to be consumed by older infants and young children. IBFAN is of the opinion that it is not possible to match the nutrients supplied by follow-up formula for older infants and for young children to their nutrient and energy needs.
6. Added sugars should be in accordance with the WHO recommendation of 5% of total energy. We agree that the percentage limit of sugars contributing to a sweet taste be converted to an absolute amount based on the energy density (g/100kcal and g/100kj) of the product for older infants and young children.
7. IBFAN agrees that the requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX Stan1-1985), the Guidelines on Nutrition Labelling (CAC/GL2-1985) and the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to the labelling of follow-up formula for older infants and to follow-up formula for young children.
8. In addition, the labelling Section 9 must clearly specify that prohibit cross branding with infant formula and the use of nutrition, health and convenience claims is clearly prohibited.
9. It is critical that the Standard states clearly that all products in powdered form are reconstituted with water not less than 70 degrees centigrade in accordance with the WHO/FAO *Guidelines on the Preparation, Storage and Handling of Powdered Infant Formulas* and the *Code of Hygienic Practice for Powdered Infant Formula for Infants and Young Children* (CAC/RCP 66-2009).
10. IBFAN does not agree with the inclusion of optional ingredients, especially ingredient such as DHA that are not supported by relevant convincing scientific evidence. If an ingredient is proven by such evidence to be safe and beneficial it should be included in the list of essential ingredients.

As mentioned above IBFAN proposes ONE standard and agrees with an overarching Preamble.

If this is not agreed then we suggest the following changes for the PROPOSED DRAFT REVISED *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987)

[PREAMBLE]

*The Codex Alimentarius Commission acknowledges the need to [**protect and support** / **recognize**] breastfeeding as an unequalled way of providing **normal** food for the healthy growth and development of infants **and young children**. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, **DELETE: ~~where [necessary / appropriate],~~** as a substitute for human milk in meeting the ~~normal~~ nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods.*

Since infant formula can continue to be used beyond 6 months, these products are not necessary.** The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children **should only be permitted if it is** ~~be~~ consistent with national health and nutrition policies and relevant national/regional legislation. **The marketing of these products** ~~and these products~~ should not discourage breastfeeding **and must be in accordance with** ~~take into account, [as appropriate,]~~ the recommendations made in the International Code of Marketing of Breast-milk Substitute**s** (1981), **and** ~~and~~ the Global Strategy for Infant and Young Child Feeding~~,~~ relevant WHO guidelines and policies, as well as relevant World Health Assembly (WHA) resolutions**, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance

on Ending the Inappropriate Marketing of Foods for Infants and Young Children. **DELETE**: ~~*that have been [endorsed / supported] by member states. [may also] provide guidance to countries in this context.*~~

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

The following comments apply to Follow-up Formula for Older Infants (Section A) and [Name of product] for Young children (Section B)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

SCOPE:

This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, ***information for use, warnings against needless and inappropriate use***, labelling and analytical requirements for Follow-up Formula for Older Infants.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / ~~shall~~] be presented as] Follow-up Formula for Older Infants

Add: 1.4 ***IBFAN does not agree with the deletion of provision 1.4 in the Scope. The scope must remind Regulatory Authorities of the safeguards contained in the over-arching Preamble if they are to ensure that the WHO recommendations underpin the marketing and labelling of each product category.***

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 Follow-up formula [for older infants] 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

3.1.2 The nutritional safety and adequacy of follow-up formula for older infants ***must*** be ~~**scientifically**~~ demonstrated, ***through relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification,*** to support growth and development of older infants.

3.1.4 c) Carbohydrates

IBFAN agrees that preferred carbohydrate should be lactose, and questions the addition of glucose polymers. We agree that Sucrose and Fructose should not be added, and question when they would be needed as a carbohydrate source. IBFAN supports the WHO recommendation for added sugars for older infants and young children, that is based on their negative effect on body weight, dental caries as well as their impact on taste development.

Maltodextrose: IBFAN opposes the addition of industrially produced carbohydrates (many of which are made from genetically modified corn). Maltodextrin (MDX), has been implicated in an increased growth of E. coli and the altering of the microbiome. It has also been linked to Crohn's Disease and diabetes related to its high glycemic index (Nickerson KP, McDonald C (2012) Crohn's Disease-Associated Adherent-Invasive *Escherichia coli* Adhesion Is Enhanced by Exposure to the Ubiquitous Dietary Polysaccharide Maltodextrin. PLoS ONE7(12): e52132. [3]

Fructose: The consumption of fructose has been linked to negative metabolic and clinical outcomes, including obesity, glucose intolerance and hepatic steatosis. Since older infants and young children may be consuming FUF products on a daily basis, these added carbohydrates with known negative effects should not be the carbohydrate sources for these products.

Footnote 4 to read:

Mono and di-saccharides, other than lactose should not exceed 5% of available carbohydrate. Sucrose, maltodextrose or fructose should not be added.

3.2 ~~**Optional**~~ **Ingredients**

[3] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0052132https://doi.org/10.1371/journal.pone.0052132).

IBFAN is opposed to the addition of optional ingredients and suggest that 3.2 is replaced with the following text:

The addition of optional ingredients may have adverse effects on child health and should not be permitted. The addition of ingredients and/or nutrients that have not been proven to be essential to the growth and development of an older infant and a young child may be an added chemical burden. Competent national and/or regional authorities wishing to alter the list of essential ingredients listed under 3.2.4 to 3.2.6, must ensure that the ingredients are evaluated and demonstrated as safe and nutritional useful by relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification.

After an extensive literature review The European Food Safety Authority (EFSA) found no scientific evidence, or insufficient evidence, to support the inclusion of many of the ingredients commonly used in formulas and promoted as having a health benefit. EFSA went further to warn that the unnecessary addition of nutrients can be a burden to a young child's metabolism.[4]

> *"If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding".*
>
> *UK Scientific Advisory Committee on Nutrition SACN 2007*

IBFAN has concerns about the lack of evidence supporting the addition of DHA:

- A meta-analysis on the use of LCPUFA concluded, "LCPUFA supplementation of infant formulas failed to show any significant effect on improving early infant cognition. Further research is needed to determine if LCPUFA supplementation of infant formula has benefits for later cognitive development or other measures of neurodevelopment." (*Qawasmi A, Landeros-Weisenberger A, LeckmanJF, Bloch MH. Meta-analysis of long-chain polyunsaturated fatty acid supplementation of formula and infant cognition. Pediatrics. 2012 June;129(6):1141-9*).
- A Cochrane review on supplementation of the LCPUFA in infant formula concluded, "The majority of the RCTS have not shown beneficial effects of LCPUFA supplementation on the neuro developmental outcomes of term infants. The beneficial effects on visual acuity have not been consistently demonstrated. Routine supplementation of term infant milk formula with LCPUFA cannot be recommended." (*Simmer K, Patole SK, Rao SC. Long-chain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database Syst Rev. 2011 Dec 7;(12): CD000376).*
- The European Food Safety Authority (EFSA), in their report published in the *EFSA Journal 2014;12(7):3760*, has explicitly stated that "*There is no necessity to add arachidonic acid, eicosapentaenoic acid, non--digestible oligosaccharides, "probiotics" or "synbiotics", chromium, fluoride, taurine and nucleotides to infant and follow--on formulae".*

Section 9 Labelling IBFAN agrees with the intent of this section.

9.5 Information for Use

9.5.1 *[Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for* ***preparation and no less than 70 degrees before being reconstituted with the powder****. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice* ***and the WHO/FAO Guidelines on the Preparation, Storage and Handling of Powdered Infant Formulas and the Code of Hygienic Practice for Powdered Infant Formula.***

9.5.2 *Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be discarded, shall appear on the label.*

9.5.3 *The label shall carry clear graphic instructions illustrating the method of preparation of the product.* ***There should be no preparation instructions showing bottles and teats for follow-up formula or for (name of the product) for young children, Graphics should only illustrate cup feeding.***

[4] *Scientific Opinion on the essential composition of infant and follow-on formulae, EFSA, EFSA Journal 2014;12(7):3760*

9.5.4 *The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use etc etc .*

9.6 Additional Labelling Requirements **REMOVE BRACKETS FROM THE FOLLOWING SAFEGUARDS. THEY ARE All ESSENTIAL**

9.6.1 *Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:*

[(a) the words "important notice" or their equivalent;]

(b) ***Breastfeeding is the normal and healthy way to feed your baby. When your baby is not breastfed she is likely to be sick more often. Exclusive breastfeeding is recommended from 0- 6 months of age, with continued breastfeeding along with appropriate complementary foods to two years of age or beyond.***

[(c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]

9.6.2 *The label shall have no pictures of infants ~~and~~ or women nor any other pictures, ~~or~~ text, ~~which idealizes the use of follow up formula. The label shall have no pictures images, text~~ or ~~other~~ representation that might:*

9.6.2.1 *idealize the* ***use of the product*** ~~*follow-up formula for older infants;*~~ *.*

9.6.2.2 *suggest* ***its*** *use for infants under the age of 6 months (including references to milestones and stages);*

9.6.2.3 *recommend or promote bottle feeding or its* ***use with a*** *bottle* ~~***feeding;***~~ *(****Preparation instructions should illustrate cups, not bottles and teats.)***

9.6.2.4 *undermine or discourage breastfeeding, ~~that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;~~*

9.6.2.5 *convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]*

9.6.3 *The terms "humanized", "maternalized" or other similar terms shall not be used.* ***[In addition, the product should not be compared to breast-milk].***

9.6.4 Products targeting babies 6 to 36 months shall not be cross branded with other infant formula or infant food products.

9.6.5 Products targeting babies 6 to 36 months must *be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes* ***REMOVE BRACKETS and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.***

9.6.6 The use of nutrition, health and convenience claims are prohibited.

All the above comments and safeguards must apply Section B – [Name of product] for Young children

INTERNATIONAL DAIRY FEDERATION (IDF)

Recommendation 3

IDF supports a minimum level for fat of 3.5 g /100 kcal.

Recommendation 4

IDF supports a maximum level of available carbohydrates of 12.5g/100 kcal

Recommendation 5

IDF supports a maximum for added sugars (excluding lactose) at 10% total energy (which equates to about 20% of available carbohydrates). This is in line with limits on sugars level recommended by the WHO (WHO, 2015). IDF can accept the use of ‘mono- and disaccharides’ in place of the word ‘sugars’ and suggests consideration of a cross-reference to the definition of sugars in CAC/GL 2-185 Guidelines on Nutrition Labelling where the same wording is used.

IDF strongly supports lactose as the preferred carbohydrate and recognises the need for suitable alternative carbohydrate types to meet the energy needs of the young child where lactose is not appropriate. IDF

recognises the preference expressed by member countries to limit the addition of ingredients with a sweet taste, however considers that this is addressed by limiting added sugars (excluding lactose) and indicating that lactose is the preferred carbohydrate. Additional wording relating to "sweet taste" is vague and subjective since there is no defined measurement. IDF believes that reference to addition of non-carbohydrate ingredients solely with the purpose of imparting a sweet taste is unnecessary in this section since there are no permissions for such additives in the General Standard of Food Additives.

Protein Quality Criteria

IDF is supportive of the action agreed by the committee that FAO *would consider convening an expert Consultation to provide guidelines on the establishment of appropriate protein quality*.

However, IDF does not consider the scope of this Consultation limited to only to PDCAAS in light of the clause that was temporarily agreed for the 12-36mo Standard until the FAO completes its review (which includes both PDCAAS and use of '*other methods that come available in the future').*

IDF remains supportive of an approach that allows for the use of the most up-to-date measures of protein quality, as per comments outlined in our earlier submission, and encourages FAO to review the most up to date evidence to ensure the Standard remains relevant noting the significant length of time that may pass before another opportunity arises to update the Standard (e.g. 1987 when FuF was last reviewed). Therefore, moving forward, guidance should be provided with the new protein quality methodology as outlined in the 2013 FAO report (FAO, 2013) .

To produce the protein nutrition needed to help feed the world requires the deployment of considerable land and other resources. Inaccurate assessment of the protein nutritional requirements resulting from inaccurate methods to determine protein quality could result in sub-optimal deployment of land and other resources. Given the importance of both the nutrition and resource use to the United Nations Sustainable Development Goals it is imperative that the most scientifically valid and accurate methods are used to determine such important characteristics as protein quality.

To this effect, IDF notes the current work[5] underway by Professor Paul Moughan, Chair of Protein Quality Expert Consultation (2013), and would recommend that the FAO Consultation considers the outcomes of this project due 2020, along with recent publications by Mathai et al 2017 and Rutherford et al 2015. This project aims to further the knowledge regarding the use of ileal digestibility amino acids method and study designs take into account recommendations of the previous FAO Expert Consultation on Protein Quality (2013). The project aims to provide further evidence to support the FAO recommended methodology.

Regarding the current clause that has been drafted into the Standard, until such time as FAO completes its review, the opening text in the footnote '*quality of protein shall not be less than 85% that of casein*' is more relevant to measurement by PER than PDCAAS or 'other methodologies'. For clarity reasons, we believe that the text should be modified to reflect this. We suggest the following wording:

> *"The quality of protein shall not be less than 85% of that of casein,* ***when PER methodology is used for protein quality determination****".*
>
> *Protein quality can also be determined by PDCAAS and 'other methodologies'*

Following the FAO Consultation, an appropriate reference for protein quality by PDCAAS and 'other methodologies' will also need to be listed.

Recommendation 9:

Many countries around the world rely on the scientific basis of standards developed by the Codex Alimentarius Commission (CAC) to facilitate international trade in food products and protect public health. Standards adopted by Codex must, therefore, maintain a science basis, facilitate harmonization of international trade and maintain an evidenced-based approach in order to remain relevant and impactful.

IDF supports the removal of the sentence "*Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context."* IDF questions the implications of embedding generalized references to WHO guidelines, guidance and policy recommendations, and WHA resolutions—past, present and future—or provisions thereof, in Codex or other international standards, particularly with the type of broad-brush approach that is currently being recommended. Recommendations included in Codex standards should be developed through the same evidence- and consensus-based processes to how Codex operates. Broad referencing of such documents into a Codex standard, without careful consideration by

[5] http://www.massey.ac.nz/massey/about-massey/news/article.cfm?mnarticle_uuid=8EFD4A9A-BE62-E5B3-C8F9-072E3035B5A0

CCNFSDU of each recommendation being referred, could lead to confusion as to the scope of the standard and how it is to be implemented by Member States.

Also, the broader topic of WHO policies and Codex mandate will be considered at the next session of the Codex Alimentarius Commission (CAC41) and assume that the end result will not contradict any decisions made at CAC. In addition, IDF supports modification of the last sentence of the first paragraph to reflect the clear differentiation of roles of Follow-up formula for older infants compared to [name of the product] for young children that has been established during this review. From a safety perspective, it needs to be clear that [name of product] for young children is not formulated as a substitute for human milk.

The Codex Alimentarius Commission acknowledges the need to [protect and support /~~recognize]~~ breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where ~~[necessary /~~ appropriate~~]~~, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods. While these products are not formulated or intended as substitutes for human milk, they should not discourage continued breast-feeding.

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, ~~[~~as appropriate,~~]~~ the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. ~~Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.~~

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Recommendation 27

IDF strongly urges the Committee to start working on NRVs for Older Infants and Young children. As a number of general principles will be the same as the ones for adult, NRVs for older infant and young children could be part of the Guideline on nutrition labelling (CAC/GL 2-1985).

The establishment of harmonised NRVs-R could inform:

- Compositional requirements / guide micronutrient composition

This is particularly important for optional nutrients for which compositional are not established in Codex standards or national legislation.

- Nutritional labelling

Conveying information regarding the nutrient content of a food on the label enables consumers to make informed nutritional choices.

- Nutritional Content Claims on food for young children:

The establishment of NRVs-R for young children could support the assessment of nutritional claims.

Recommendation 32 (or 33)

In addition to the current labelling requirements detailed in Section 9.5 (or section 9.6) for [name of product] for young children, IDF supports a proposal for the inclusion of a statement that '**products covered by this standard are not a substitute for human milk and shall not be presented as such**.'

Although strong divergent opinions were expressed on this issue, a very clear majority of the eWG was of the opinion that due to the diet pattern of a young child, this product could not be considered as a substitute for human milk.

(Name of product) for young children is not a sole source of nutrition nor can it be given from birth.

(Name of product) for young children is not developed to be able to satisfy by itself the nutritional needs of a young child. The composition takes into account the role of the product as described by the 3 principles agreed by the committee during the 38th session of CCNFSDU, which position the product as a complementary liquid part of the diet of young children:

- contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate; and/or

- contribution of adequate amounts of key nutrients from milk, and if appropriate breast-milk, where such nutrients are key contributors to the diet of young children; and/or
- the nutritional quality and integrity of product to ensure nutritional safety.

Additionally, young children consume general foods and it would be inconsistent to create a distortion whereby [name of the product] for young children could not benefit from the use of making claims whilst other general food which are not tailored to be consumed by young children could.

References:

FAO (2013) Dietary protein quality evaluation in human nutrition: Report of an FAO Expert Consultation, FAO Food and Nutrition Paper 92. Rome: FAO.

Mathai JK, Liu Y, Stein HH. (2017). Values for digestible indispensable amino acid scores (DIAAS) for some dairy and plant proteins may better describe protein quality than values calculated using the concept for protein digestibility-corrected amino acid scores (PDCAAS). British Journal of Nutrition, 117(4), 490–499. https://doi.org/10.1017/S0007114517000125

Rutherfurd SM, Fanning AC, Miller BJ & Moughan PJ. (2015) Protein digestibility-corrected amino acid scores and digestible indispensable amino acid scores differentially describe protein quality in growing male rats. Journal of Nutrition, 145, 372-379. doi: 10.3945/jn.114.195438

INSTITUTE OF FOOD TECHNOLOGISTS (IFT)

IFT is submitting comments that it can support on scientific basis. As for recommendations related to the structure of the standard and inclusion of non-Codex texts, IFT finds that they fall into the realm of national/regional policy making which is not in IFT's scope of mission; thus, we do not offer comment on this aspect.

(i) Specific comments

Recommendation 1:

IFT supports the revised protein requirements based on the rationale presented to the eWG by one Codex Member Organization (CMO) that protein quality of complementary foods was of sufficient amounts and quality to support adequate overall dietary protein intake. We note that human milk provides 1.47 g protein/100 kcal (0.35 g protein/100 kJ), and cow's milk provides 5.12 g protein/100 kcal (1.22 g protein/100 kJ) (values calculated from a U.S. Department of Agriculture (USDA) database (https://ndb.nal.usda.gov/ndb/); hence, the reduction in protein content would render the beverage more similar to human milk.

Recommendation 2:

This recommendation relates to addition of the optional ingredient docosahexaenoic acid (DHA). Discussion surrounding this optional ingredient focused on setting amounts as described on p. 10 of the eWG review; specifically "In 2015, CCNFSDU37 wished to further consider establishing a minimum level to guide the voluntary addition of DHA for the purposes of ensuring that the product contains sufficient amounts to achieve the intended effect (REP16/NFSDU para 58(d))." the purpose of which was to assist national and/or regional authorities when considering Principle 3.2.2 for the optional addition of ingredients:

3.2.2 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.

Note: Human milk contains 3 – 5% fat (FAO 2010) of which an average of 0.32% of fatty acids are DHA (Brenna et al. 2007). Energy content of human milk is 60 – 75 kcal/100 ml (Jenness 1979).

The eWG review document further notes FAO-recommended adequate intakes of long-chain polyunsaturated fats of between 0.2 – 0.36% of total fatty acids; whereas EFSA has concluded that 100 mg of DHA per day is adequate for the majority of infants (EFSA 2014). The FAO (2010) document considers that during the 6 – 24 month age range total dietary energy from fat tapers off from an initial 40 – 60% of total calories to 35% of calories (see Table 2.2, p. 12).

Given the assumption inherent in the FAO values that fat contributes at least 35% of energy intake, the rationale behind the application of a fixed percentage of total fatty acids to calculate DHA addition to formula of widely varying total fat content as shown in Table 7 of the eWG review document is obscure. That approach generates values that are widely divergent from the EFSA value. On the other hand, the EFSA value suggestion can be shown using values for human milk-fat content, average DHA proportion in human milk, and FAO-identified energy intakes by older infants, of which half are contributed by human milk (Forsyth et al. 2016). Using these parameters, the physiologically relevant range for inclusion per the intent

of Principle 3.2.2 is 14 – 24 mg/100 kcal, or 20 mg/100 kcal as an intermediate value. The calculations that follow show how IFT arrives at these numbers.

Calculate mg of fat in 100 mL breast milk:

Lower range: 100 mL x 3% = 3000 mg fat/100 mL human milk

Higher range: 100 mL x 5% = 5000 mg fat/100 mL human milk

Calculate mg of DHA (on average) in 100 mL breast milk:

Lower range: 3000 mg fat/100 mL human milk x 0.32% = 9.6 mg DHA /100 mL human milk

Higher range: 5000 mg fat/100 mL human milk x 0.32% = 16 mg DHA /100 mL human milk

Calculate factor to convert mg/100 mL to mg/100 kcal using midpoint value (67.5 kcal/100 mL) from (Jenness 1979):

Conversion factor = 100 kcal/67.5 kcal/100 mL human milk = 1.48

Conversion factor = 4.184 kJ/kcal

Lower range: 9.6 mg DHA/100 mL human milk x 1.48 = 14.2 mg/100 kcal (3.4 mg/100 kJ) Higher range: 16 mg DHA /100 mL human milk x 1.48 = 24 mg/100 kcal (5.7 mg/100 kJ)

Using the 20 mg DHA/100 kcal provided as formula provides DHA in proportion to energy intakes in amounts nearing (6 – 12 months) and meeting (1 – 3 years) EFSA recommendations (Table 1).

Table 1. Daily energy requirements for boys and girls 6 – 36 months (FAO 2001) and calculated DHA intake at 20 mg DHA/100 kcal (4.78 mg/100 kJ)

	Daily energy requirements (kcal/day)		**DHA intake [1] (mg/day)**	
Age	**Boys**	**Girls**	**Boys**	**Girls**
6–7 months	636	584	63.6	58.4
7–8 months	664	612	66.4	61.2
8–9 months	688	637	68.8	63.7
9–10 months	710	658	71	65.8
10–11 months	731	679	73.1	67.9
11–12 months	753	698	75.3	69.8
1 to 2 years	948	855	94.8	85.5
2 to 3 years	1129	1047	112.9	104.7
Weighted Average (6–36 months)	970	890	97	89

1. DHA intake assumes that formula containing 20 mg DHA/100 kcal (4.78 mg/100 kJ) provides about half of daily energy intake. Note: values would be lower if calculations are made using 500 mL per day consumption volume as the calculation basis.

The calculations in Table 1 show that on average over the 6 – 36 months interval, older infants and young children would consume 100 mg DHA per day when 20 mg/100 kcal (4.8 mg/100 kJ) is included in the formulated product. Notably, the weighted average daily intake for older infants and young children during this same time frame would be 60.5 mg if the 13 mg/100 kcal (3.1 mg/100 kJ) suggested in the review document were used. For the reasons provided above, IFT does not support either option 1 or 2 because neither meets the expectation articulated in principle 3.2.2. Moreover, both use a flawed interpretation of FAO recommendations in their calculations. Furthermore, no science-based rationale is provided for the statement in the eWG review document.

"*… it is recommended that 13 mg/100 kcal is adopted as the minimum for the voluntary addition of DHA as that gives the widest range for addition also noting that the footnote allows competent national and/or regional authorities to deviate from the conditions, as appropriate for their local population.*"

IFT does not understand this recommendation as this portion of the standard aimed to give guidance to those countries and regions that may not in fact have access to infrastructure and resources to

independently determine intakes or needs. It is unclear what drives the stated need for width of range. In a separate comment the eWG review document states the following:

"…minimum values for optional ingredients have not been established for any other optional ingredients listed in either the Codex Infant Formula Standard, or the proposed draft Standard for Follow-up Formula (REP16/NFSDU Appendix III)."

While this statement accurately describes these two standards, IFT would remind the committee that the establishment of minimum values for optional ingredients within other Codex documents relevant to this age group has clear precedent. For example, the Codex Guidance on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991) provides for optional addition of vitamins and minerals and notes the following:

"6.6.1.3 If the dietary intake data for the target population is not available, the vitamins and minerals listed in the Table in the Annex to these Guidelines can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food."

Values for Guidance Upper Level (GUL) for DHA:

IFT bases its support on the highest observed DHA concentration in breastmilk (around 1% DHA total fat) which appears to be safe for older infants (Brenna 2007). Human milk provides 6.26 g fat/100 kcal (per the USDA database https://ndb.nal.usda.gov/ndb/) which would suggest that upwards of 63 mg DHA/100 kcals (15 mg DHA/100 kJ) is physiologically allowable. Using the variable amounts of fat possible in follow-up formula, 1% DHA would equate to 44 mg/100 kcal, (10.5 mg DHA/100 kJ) to 60 mg/100 kcal, (14.3 mg DHA/100 kJ). The value of 50 mg/100 kcal (12 mg/100 kJ) falls between these values and is below the highest observed DHA concentration in breastmilk (Brenna 2007).

To be better understand daily intakes of DHA from formulated products containing either 30 mg DHA/100 kcal, (7.17 mg DHA /100 kJ), or 50 mg DHA/100 kcal, (11.95 mg DHA/100 kJ), we calculated intake values shown in Table 2 using the same assumptions as in Table 1.

Table 2. Daily intakes of DHA based on daily energy requirements for boys and girls 6 – 36 months of age (FAO 2001) and calculated DHA intake at 30 mg DHA/100 kcal (4.78 mg/100 kJ) and 50 mg/100 kcal (11.95 mg/100 kJ)

Daily energy requirements (kcal/day)[1]			DHA intake [2] (mg/day)		DHA intake [3] (mg/day)	
Age	**Boys**	**Girls**	**Boys**	**Girls**	**Boys**	**Girls**
6–7 months	636	584	95.4	87.6	159	146
7–8 months	664	612	99.6	91.8	166	153
8–9 months	688	637	103.2	95.55	172	159.25
9–10 months	710	658	106.5	98.7	177.5	164.5
10–11 months	731	679	109.65	101.85	182.75	169.75
11–12 months	753	698	112.95	104.7	188.25	174.5
1 to 2 years	948	855	142.2	128.25	237	213.75
2 to 3 years	1129	1047	169.35	157.05	282.25	261.75
Weighted Average (6–36 months)	970	890	145.5	133.5	242.5	222.5

1. Assumes formulated product provides about half of daily energy intake. Note: values would be lower if calculations are made using 500 mL per day consumption volume as the calculation basis.
2. Assumes 30 mg/100 kcal (7.17 mg/100 kJ)
3. Assumes 50 mg/100 kcal (11.95 mg/100 kJ)

Intakes of formulated product containing 50 mg DHA/100 kcal (11.95 mg DHA/100 kJ) never exceed the 250 mg/day recommended for 2 – 18 year olds by EFSA (EFSA Panel on Dietetic Products and Allergies 2010).

On the basis of global human milk data, it is scientifically relevant and physiologically appropriate to consider that 50 mg/100 kcal (12 mg/100 kJ) is a suitable concentration to be set as a GUL for DHA in follow-up formula.

IFT supports the revision of the current draft standard as shown below as these values are grounded in measured compositional values of human milk and physiologic intakes of infants as determined by WHO, FAO, and transparent peer-reviewed literature.

Docosahexaenoic acid (DHA) note			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	- **(note)**	- **(note)**	~~**[30]**~~ **50**
mg/100 kJ	-	-	~~**[7.9]**~~ **12**
note If docosahexaenoic acid (22:6 n-3- ; **DHA)** added to follow-up formula, a minimum level of ~~**13 mg/100 kcal (3.1 mg/100 kJ)**~~ **20 mg/100 kcal (4.8 mg/100 kJ)** should be reached and arachidonic acid (20:4 n-6- ; **ARA)** content should reach at least the same concentrations as docosahexaenoic acid. The content of eicosapentaenoic acid (20:5 n-3), which ~~**can**~~ **may** occur in sources **of n-3 LC-PUFA** added as a source of DHA**,** should not exceed the content of DHA. Competent national and/or regional authorities may deviate from the above conditions**,** ~~**as**~~ **if substantiated** ~~**appropriate**~~ **to address** ~~for~~ the nutritional needs **of the national/regional populations.**			

IFT would like to further add its strong support for the mandatory addition of ARA when DHA is added because there is no history of safe use of formulas supplemented solely with up to 1% DHA. While infant and follow-up formula providing both DHA and ARA have been evaluated in numerous controlled trials, the use of formula with up to 1% DHA and no ARA would be a novel product offering that has not been systematically evaluated nor clinically assessed for its effects, suitability, and safety (Koletzko et al. 2015). The appropriateness of ARA addition when DHA is added to follow-up formulas was highlighted by several expert authorities such as the U.S. Food and Drug Administration.

Recommendations 3 – 6 relate to variability allowed in the macronutrient composition. In committee discussions this older infant age range has been presented as being nutritionally well served by either human or cow's milk. IFT has based its support on whether or not the suggestions fall within the compositional parameters of these two beverages.

Recommendation 3:

IFT agrees to establishing a minimum fat level of 3.5 g/100 kcal (0.84 g/100kJ), as this would relate to a fat level similar to that found in low-fat (2% fat) cow's milk.

Recommendation 4:

IFT agrees to establish a maximum available carbohydrate (CHO) level of 12.5 g/100 kcal (3.0/100 kJ), as human milk provides 9.8 g CHO/100 kcal and cow's milk 7.27 g CHO/100 kcal.

Recommendations 5 & 6:

IFT agrees to the provisions of recommendations 5 and 6, as lactose comprises greater than 90% of carbohydrate in both human and cow's milk.

Recommendation 7:

IFT does not support the omission of a calcium-to-phosphorous (Ca:P) ratio in products for this age group. While diet is becoming progressively more diverse in older infants, milk (human or animal) remains a significant nutritional source for which there is a Ca:P value; in the case of cow's milk the ratio is 1.3 and in human milk an even greater ratio of 2.2 is observed.

Recommendation 8:

IFT recognizes the diversity of opinion regarding Vitamin D amounts relative to geographic location of some countries. We note that human milk is typically low in Vitamin D even in Vitamin D-adequate mothers. We could support this recommendation but suggest addition of language to allow deviation from stated values by competent national or regional authorities.

Recommendation 10 – 15, related to the structure of the standard:

- IFT agrees that recommendation 10 provides a clear and concise statement as to which foods this

standard applies for use in section 1.1.

- IFT agrees with recommendation 11, the suggested statement for section 1.2 and omission of square brackets surrounding “labelling and analytical.”
- IFT agrees with recommendation 12, the recommended statement for product naming in section 1.3 preferring the more prescriptive “shall.”
- IFT agrees with recommendation 14, the statement and inclusion of specific Codex texts related to labelling and health claims in the introductory section of the labelling section.
- IFT agrees with recommendation 15, to not delay work on the standard until nutrient reference values (NRVs) for infants and children are set and agree to revisit as necessary as part of the Terms of Reference (ToR) for an NRV working group.

Recommendation 16:

IFT prefers option 2, because it conveys the same instruction more succinctly as 9.13 states explicitly that sources of protein must be named. In 9.1.5, IFT supports removal of the square brackets around “shall” and striking of the word “may.”

Recommendations 17 – 21, related to labelling sections of the standard:

- IFT agrees with recommendation 17 regarding the listing of ingredients and statement of ingredient origin including the use of International Numbering System (INS) numbers.
- IFT agrees with recommendation 18 regarding wording of section 9.3 declaration of Nutritive Value with removal of square brackets around “as well as” and deletion of “or” in both subsection a) and b).
- IFT agrees with recommendation 19 regarding necessary modification of date marking in accordance with expected CCFL44 recommendations.
- IFT agrees with recommendation 20 regarding rewording provisions for use with some further edits, namely

  9.5.1: remove square brackets around “Ready to use,” “either,” “powdered products,” replace the word “safe” with “potable” and delete clause “or has….before feeding.” We agree with the striking the follow-on text as indicated.

  9.5.2: remove square brackets around product.

  9.5.6: retain portion of text stating “The label…..of age.” Strike the remainder of text, as complementary feeding would be typical at these older ages.

- IFT agrees with recommendation 21 regarding additional labeling with some edits.

  9.6.1: remove square brackets around provision a). Strike provision d).

  9.6.2 and 9.6.3: remove square brackets and strike text as indicated in recommendation.

  9.6.4: bolded text in square brackets should be struck, as it is redundant to earlier text “Products shall be labeled in such a way as to avoid ***any risk*** of confusion between……(emphasis added).

Recommendations 22 – 27, related to the structure of the standard for [name of product] for young children:

IFT notes that of the two age-defined product categories, the committee clearly articulated a perspective that young children, as opposed to older infants, are expected to have a substantially more diverse diet. In addition, the committee sentiment seemed to be to consider that this increased dietary diversity allowed for greater flexibility in product composition.

- IFT agrees that recommendation 22 provides a clear and concise statement as to which foods this standard applies for use in section 1.1.
- IFT agrees with recommendation 23, the suggested statement for section 1.2 and omission of square brackets surrounding “labelling and analytical.”
- IFT agrees with recommendation 24, the recommended statement for product naming in section 1.3 preferring the more prescriptive “shall.”
- IFT agrees with recommendation 26, the statement and inclusion of specific Codex texts related to

labelling and health claims in the introductory section of the labelling section.

- IFT agrees with recommendation 27, to not delay work on the standard until NRVs for infants and children are set and agree to revisit as necessary as part of the the ToR for a NRV working group.

Recommendation 28:

IFT prefers option 2, as it conveys the same instruction more succinctly as 9.13 states explicitly that sources of protein must be named. In 9.1.5, IFT supports removal of the square brackets around "shall" and striking of the word "may."

Recommendations 29 – 36, related to labelling sections of the standard:

- IFT agrees with recommendation 29 regarding the listing of ingredients and statement of ingredient origin including the use of INS numbers.
- IFT agrees with recommendation 30 regarding wording of section 9.3 declaration of Nutritive Value with removal of square brackets around "as well as" and deletion of "or" in both subsection a) and b). In subsection c) remove square brackets.
- IFT agrees with recommendation 31 regarding necessary modification of date marking in accordance with expected CCFL44 recommendations.
- IFT agrees with recommendation 32 regarding rewording provisions for use with some further edits, namely:

  9.5.1: remove square brackets around "Ready to use," "either," "powdered products," replace the word "safe" with "potable" and delete clause "or has….before feeding." We agree with the striking the follow-on text as indicated.

  9.5.2: remove square brackets around product.

  9.5.6: retain portion of text stating "The label…..of age." Strike the remainder of text, as complementary feeding would be typical at these older ages.

- IFT agrees with recommendation 33 regarding additional labeling with some edits.

  9.6.1: bolded text in square brackets should be struck, as it is redundant to earlier text "…shall have ***no image, text or representation*** that could undermine..." Feeding bottles would be an image or a representation.

  9.6.2: bolded text in square brackets should be struck, as it is redundant to earlier text "Products shall be labeled in such a way as to avoid ***any risk*** of confusion between……(emphasis added).

Recommendation 34, definition of follow-up formula for older infants:

IFT supports removal of the square brackets and forward slash between progressively and diversified. This change would require the additional word change of "as" for "when."

Recommendation 35, definition of [name of product] for young children:

IFT supports removal of the square brackets around "formulated" and the square brackets around "progressively" and "diversified." Delete the remainder of bolded text in square brackets and make a full stop to the sentence after "diet of young children."

Recommendation 36:

IFT supports adoption of the name Follow-up Formula for Older Infants for the 6 – 12 month age group.

Recommendation 37:

IFT supports adoption of the name Formulated Drink for Young Children for the 12 – 36 month age group.

References

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Forsyth, S., Gautier, S., and Salem, N., Jr. (2016). Global Estimates of Dietary Intake of Docosahexaenoic Acid and Arachidonic Acid in Developing and Developed Countries. *Ann Nutr Metab* **68**, 258-67.

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INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

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

Recommendation 1:

ISDI welcomes the introduction of the minimum level of 1.6g protein/100kcal in the table instead of in a footnote and supports the proposed addition of *[or non-goats']* in footnote 5. However ISDI has concerns about the wording of footnote 6 and suggests the following modification (in bold):

> [6] Follow-up formula based on non-hydrolysed milk protein containing [less than 1.8 g] protein/100 kcal [(0.43 g/100 kJ)] and follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] (0.54 g/100 kJ) should be **scientifically substantiated, clinically evaluated when needed, and assessed** ~~be clinically evaluated~~ by a competent national and/or regional authority.]

Rationale

Taking into account that in some low income countries intake of complementary foods with sufficient quality and quantity may be low, ISDI supports a footnote requiring that follow-up formulas containing levels of protein less than 1.8g/100kcal be scientifically substantiated in order to guarantee safety and suitability for the targeted population in the context of the overall local/regional diet.

The following should be considered:

1. ISDI considers that the term '*Scientifically substantiated'* acknowledges that data set reviewed as basis of assessment should not be limited to clinical evaluation data. Relevant protein intake data and other considerations for the specific/relevant country need to be considered. As an illustration, the EFSA opinion on safety and suitability of formula for older infants with a protein content of at least 1.6g/100kcal was based on consideration of breast milk protein levels, protein requirements and evidence from population surveys of sufficient protein intakes in Europe in addition to the clinical data from the formulation assessed.
2. ISDI supports the fact that national/regional authorities assess the scientific substantiation for a given formula in the context of the overall local/regional diet, but Codex Standards relating to products do not usually describe how the evaluation should be performed. If the Committee wishes to be more specific, ISDI considers it is important to reflect roles of authorities versus manufacturers accurately.

   Indeed, when required, competent national and/or regional authorities generally assess the scientific substantiation presented by formula manufacturers. This substantiation may include data from clinical studies performed by the manufacturer itself, but it is not the role of the competent authority to perform clinical trial on specific products.

   It is worth noting that, on this matter, the Infant Formula Standard is not more prescriptive than the proposed wording for formula for older infants.
3. More precisely on its proposal that follow-up formula should be clinically evaluated *"**when needed**",* ISDI considers that, as a wider body of evidence becomes available, clinical evaluation may become redundant, therefore 'when needed' is important to reflect this.

References

EFSA. Scientific opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal. Adopted 5 April 2017.

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Recommendation 2:

ISDI supports the optional addition of DHA however notes the challenge of setting a global minimum and highlights the lack of scientific consensus on the mandatory link between ARA and DHA. ISDI therefore reiterates its previous position that **the setting of a minimum level should be left to the consideration of national authorities** due to the variability of DHA intake in the diversified diet of older infants.

ISDI does not support mandatory addition of ARA when DHA is added and therefore proposes to change footnote 20 as follows:

> [20)] If docosahexaenoic acid (22:6n-3) is added to follow-up formula, ~~a minimum level of [13 mg/100 kcal (3.1 mg/100 kJ)] should be reached, and~~ **the addition of** arachidonic acid (20:4 n-6) ~~contents should reach at least the same concentrations as DHA docosahexaenoic acid. The content of~~ **and** eicosapentaenoic acid (20:5 n-3), ~~which can occur in sources of LC-PUFA~~, **is optional**. **If eicosapentaenoic acid is added, its content** 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 of their local population.

Consequently, the ISDI proposed footnote would read:

> [20)] If docosahexaenoic acid (22:6n-3) is added to follow-up formula, the addition of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3), is optional. If eicosapentaenoic acid is added, its content 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 of their local population.

Rationale

ISDI supports the optional addition of DHA, taking into consideration that several expert opinions have:

- Established nutritional requirements for DHA and concluded that the dietary DHA intake may be low in older infants, consequently support supplementation of older infant's diets, including follow-up formula for older infants (AFSSA, 2010; FAO, 2010; EFSA, 2013; Koletzko, 2013; EFSA, 2014);
- Recommended DHA intake levels associated with beneficial health outcomes (AFSSA, 2010; FAO, 2010; EFSA, 2014).

However, ISDI also emphasizes that due to the global variability of dietary DHA intakes, it remains challenging to establish one global recommendation for a minimum DHA level where DHA is added to Follow-up Formula for older infants as highlighted by Brenna (2008).

Regarding ARA, ISDI considers that there is neither sufficient evidence nor scientific consensus to define strict criteria for the levels of ARA when DHA is added (ENA, 2012; EFSA, 2013; EFSA, 2014). For instance the current practice in the US of adding ARA when DHA is added to **infant formula products for 0-12 month** olds has been accepted by the US FDA as safe. In contrast, EFSA specifically considered it is not required to add ARA when DHA is added to infant and follow-on formula (EFSA, 2014), ISDI therefore requests that the mandatory link between DHA and ARA be re-opened as there is not sufficient scientific consensus for such a provision.

Additionally, considering that the nutritional requirements and the role of [name of product] for young children are vastly different from older infants, the recommendations by expert bodies for older infants may not apply for young children, as it is the case for DHA. Therefore, ISDI is of the opinion that for the optional addition of DHA in [name of the product] for young children, the principles for the addition of optional ingredients as described in section 3 should be followed.

References

AFSSA (Agence Française de Sécurité Sanitaire des Aliments) AFSSA opinion regarding dietary nutrient recommendations for fatty acids. AFSSA – 2006-SA-0359. 2010

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Yuhas R, Pramuk K, Lien EL. Human milk fatty acid composition from nine countries varies most in DHA. Lipids 2006;41:851–8

Recommendation 3:

ISDI supports this recommendation.

Recommendation 4:

ISDI reiterates its previous position to **support a maximum level of available carbohydrates at 14 g/100 kcal** instead of 12.5 g/100 kcal. This is aligned with several eWG member responses, expert opinions (ENA, ESPGHAN), recommendations from recognised authoritative scientific bodies (FAO/WHO, IoM, EFSA), and nutrient requirements for young children to support a level that is scientifically substantiated.

ISDI does not support a maximum level of 12.5 g/100 kcal for available carbohydrate as there is no scientific rationale to support maximum levels below 14 g/100 kcal.

In addition, ISDI maintains that the maximum carbohydrate level of 14 g/100 kcal

- meets all of the objectives of the eWG and achieves nutritionally balanced composition for [name of product] for young children;
- is aligned with the approach taken to set the maximum carbohydrate level in infant formula and the revised requirements for follow-up formula for older infants as specifically noted by the eWG (i.e. based on residual energy calculations once the minimum amounts of protein and fat were established);
- does not significantly increase the potential amount of sugars other than lactose that could be added to [name of the product] for young children.

  Considering recommendation 5: mono- and disaccharides are limited to 20% of carbohydrate. The difference between 12.5 g and 14 g/100 kcal is 1,5g carbohydrate, 20% of which would be 0,3g mono- and disaccharides.

  Limits for available carbohydrate and sugars should be assessed independently.

Rationale

ISDI welcomes the nutrient modelling approach taken by countries at CCNFSDU38 to assess possible consequences to macronutrient levels in product formulations as a result of limits set on available carbohydrates for [name of the product] for young children.

The current Codex Standard for Follow-up Formula has a minimum protein level of 3 g/100 kcal. Given the increasing body of evidence suggesting that protein requirements of young children are lower than previously estimated, CCNFSDU has lowered the minimum protein accordingly to 1.8 g/100 kcal.

This is a substantial reduction in protein compared to current regulations in many parts of the world that can have major implications to formulations when protein and maximum available carbohydrate levels are lowered. This is further illustrated by the levels in follow-up formula for older infants and modelling exercises on why carbohydrate level at 14 g/100 kcal becomes important when lowering protein levels.

eWG concerns

ISDI has highlighted that the key objectives of the eWG are met even when carbohydrate level is 14g/100 kcal and ISDI has provided justification in support of this level.

ISDI also notes that while several members of the eWG had supported a maximum carbohydrate level of 14 g/100 kcal, the members supporting values lower than 14 g/100 kcal had concerns either based on levels of added sugar intake or referencing levels of carbohydrate to that of cows' milk and therefore ISDI would like to address these concerns.

1) There seems to be confusion with respect to the science regarding carbohydrates and sugars. The permitted *level* of available carbohydrate is a different provision than the *type* of permitted carbohydrate. Concerns about added sugar cannot simply be addressed by reducing the maximum carbohydrate level and this has been acknowledged by the chairs of the eWG. More precisely, if the maximum level for added sugars is 20% of available carbohydrate, the potential difference in amount of sugars others than

lactose, between a product with a level of carbohydrates of 12.5 vs. 14 g/100 kcal would be insignificant (difference of 0.3 g/100 kcal).

In the interest of young child health, ISDI supports limiting added sugars in [name of the product] for young children as this addresses any concerns about the nutritional profile of the products. Thus, while supporting restricting added sugars, ISDI urges the committee to evaluate maximum carbohydrate level and sugars independently.

2) Regarding reference to cows' milk levels for carbohydrate, ISDI does not support that the maximum carbohydrate for [name of product] for young children should be based solely on cow's milk. ISDI would like to remind the committee that the protein content of cows' is much higher at an average of 5.4 g/100 kcal and 7.3 g/100 kcal (CP2, 2016) for full fat and reduced fat cows' milk respectively, therefore using cows' milk as a reference only for carbohydrates would not be appropriate since the minimum protein has been set at a much lower 1.8 g/100 kcal. Thus, it is even more imperative to permit flexibility and consider all macronutrients together with respect to their contribution to energy.

3) ISDI also notes the comment by the Committee, "*that breast milk, formulas for infants and cow's milk are all suitable for the young child age group, and as such any levels specified in the standard would need to accommodate these foods*." Both the infant formula standard and revised requirements for follow-up formula for older infants contain 9-14g/100kcal available carbohydrates. Therefore, the proposed maximum carbohydrate level of 14g accommodates more closely these foods, also suitable for young children as advised by the Committee.

Modelling

ISDI has conducted the macronutrient modelling with the protein minimum of 1.8 g/100 kcal and fat minimum of 3.5 g/100 kcal as proposed at CCNFSDU38 and further compared to the energy (%E) from international recommendations. ISDI has compared carbohydrate maximums of 12.5 and 14 g/100 kcal. ISDI has also conducted modelling with a minimum protein level of 1.5 g, as previously proposed.

Table 1 shows if the maximum carbohydrate level is 12.5 g/100 kcal and the minimum protein is 1.8 g/100 kcal, the residual fat is 4.8g/100kcal (42.8% energy). Table 2 shows if the maximum carbohydrate level is 12.5 g/100 kcal and the minimum fat is 3.5 g/100 kcal, the residual protein is 4.6 g/100 kcal (18.5% of energy). Both scenarios result in much higher energy intakes from fat or protein than international recommendations and national regulations.

Hence, restricting maximum carbohydrate level at 12.5 g/100 kcal does not enable flexibility in formulating nutritionally balanced products that addresses the nutritional needs of young children globally.

TABLE 1: Modelling exercise showing the effect on minimum fat at different maximum carbohydrate levels when protein levels are 1.8 g/100 kcal

	Product 1		*Product 2*	
Low protein	*g/100 kcal*	*% E*	*g/100 kcal*	*% E*
Carbohydrate	12.5	50	14	56
Fat	4.8	42.8	4.1	36.8
Protein	1.8	7.2	1.8	7.2

TABLE 2: Modelling exercise showing the effect on minimum protein at different maximum carbohydrate levels when fat levels are at 3.5 g/100 kcal

	Product 3		*Product 4*	
Low fat	*g/100 kcal*	*% E*	*g/100 kcal*	*% E*
Carbohydrate	12.5	50	14	56
Fat	3.5	31.5	3.5	31.5
Protein	4.6	18.5	3.1	12.5

TABLE 3: Comparison of products with carbohydrate (CHO) values of 12.5g and 14g (in TABLE 1 and TABLE 2) against international recommendations for AMDR (FAO/WHO 2002 & 2010, FAO/WHO/UNU, 2007, EFSA, 2013; IoM, 2002; Suthutvoravut et al, 2015)

% E	**Product formulations**				**Recommendations for young children (1-3 yrs)**			
	12.5g CHO		**14g CHO**		**%E**			
	Product 1	**Product 3**	**Product 2**	**Product 4**	**EFSA[6]**	**IoM[7]**	**FAO /WHO**	Suthutvoravut, 2015 / **ENA[8]**
CHO	50	50	56	56	45-60	45-65	55-75[9]	36-56
Fat	42.8	31.5	36.8	31.5	35-40	30-40	35[10]	40-55
Protein	7.2	18.5	7.2	12.5	6-15	5-20	6[11]	6-10

TABLE 3 demonstrates that all products formulated with a carbohydrate level of 14 g/100 kcal is nutritionally the most suited to the AMDRs of international recommendations while maintaining the nutritional integrity. Formulations with protein levels at 1.8 g/100kcal and carbohydrate levels below 14 g/100kcal would not be aligned with daily recommendations as the % of energy from fat would result in much higher values compared to FAO/WHO, EFA and IoM recommendations.

In this context, ISDI notes that the eWG has not taken the approach taken by other Codex Standards, such as Codex Standard for Infant Formula and Follow-on Formula, EFSA and ENA which sets maximum carbohydrate levels based on residual energy once minimum protein and fat levels are established. While this approach would actually lead to a residual carbohydrate level of 15.3 g/100 kcal, ISDI can however agree with a maximum level of 14 g/100 kcal available carbohydrates.

In conclusion ISDI supports a maximum value of 14 g/100 kcal for available carbohydrates in [name of the product] for young children based on alignment with other regulations and expert recommendations, and does not support values lower than 14 g/100 kcal.

Additional comment

While ISDI position for minimum protein is set at **1.5 g/100 kcal**, the modelling exercise was conducted using the minimum protein level of 1.8 g/100 kcal as currently proposed. However we would like to point out that at 14 g carbohydrate and 1.5 g/100 kcal, the residual fat is 4.2 g/100 kcal (acceptable macronutrient distribution ranges: fat 38%; protein 6%; CHO 56%). This is demonstrated in TABLE 4. This is similar to the residual fat (4.1 g/100kcal) when protein is set at 1.8 g/100 kcal. In so saying, both protein values (1.5 g and 1.8 g protein) do not change the outcome of the modelling exercise that highlights the need for 14 g/100 kcal for maximum of available carbohydrate.

TABLE 4: Modelling exercise showing the effect on minimum fat for low protein formulas containing 1.5 g / 100 kcal at different maximum carbohydrate levels.

LOW PROTEIN	g/100 kcal	% E	g/100 kcal	% E	g/100 kcal	% E

[6] EFSA Panel on Dietetic Products. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408.
[7] IoM (Institute of Medicine). Dietary reference intakes for energy, carbohydrate, fibre, fat, fatty acids, cholesterol, protein and amino acids. Food and Nutrition Board, Institute of Medicine. National Academies Press; 2002
[8] Recommendations of an international expert group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy (Suthutvoravut, 2015). The repartition of energy as proposed here refers to the product while the other recommendations refer to the total diet.
[9] WHO/FAO Population nutrient intake goals for total CHO is 55-75% (WHO/FAO, 2003), with a 2007 Scientific Update suggesting a lower bound of 50% CHO from energy could also be appropriate (Mann, 2007).
[10] FAO/WHO: Total Fat AMDR for 6-24mo is *reduced to* 35% energy (from 40-60% energy from fat for 0-6mo infants) and for 2 -18years is 25-35%. (FAO/WHO, 2010).
[11] Based on protein requirements for young children (12-36 months) calculated from WHO/FAO/UNU protein requirements (WHO/FAO/UNU, 2007) using WHO weight-for-age growth standards (WHO, 2006). No upper limit for protein is set.

Carbohydrate	12.0	48	12.5	50	14.0	56
Fat	5.2	46	4.8	44	4.2	38
Protein	1.5	6	1.5	6	1.5	6

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WHO Multicentre Growth Reference Study Group. WHO Child Growth Standards: Length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age: Methods and development. Geneva: World Health Organization, 2006

Recommendation 5:

ISDI favours having the maximum added sugar expressed as a % of energy, but for the purpose of responding to this recommendation, ISDI supports a maximum of added sugars (excluding lactose) of 20% of available carbohydrates (which is about **10% total energy**). This is in line with limits on sugars level recommended by the WHO (WHO, 2015).

ISDI strongly supports restricting added sugars other than lactose and can accept the use of 'mono- and disaccharides' instead of the word 'sugars' as proposed in this recommendation in alignment with the definition of sugars in CAC/GL 2-185 Guidelines on Nutrition Labelling. However, ISDI finds the last three sentences proposed for footnote 4 confusing and not adding value. Therefore ISDI suggests deleting them; footnote 4 would then read:

> 4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, should not exceed 20% of available carbohydrate. ~~Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.~~ ~~Sucrose and/or fructose [and/or other carbohydrates contributing to the sweet taste of [name of product]] should not be added, unless needed as a carbohydrate source. [Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]~~

Rationale

The sentence *"Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate"* should be deleted as it is not necessary and might lead to misinterpretation. Sugars (nutrients) are defined in Codex Standard CAC/GL2-1985. Consequently, there is no need to focus on some ingredients containing sugar given there is already a provision on the maximum level of sugars.

In the sentence: *[Sucrose and/or fructose should not be added, unless needed as a carbohydrate source],* the wording *"unless needed as a carbohydrate source"* is subject to interpretation and is redundant since the addition of sucrose and fructose is restricted by the limit to be set for mono- and disaccharides.

Furthermore, it appears that the text relating to sucrose and fructose has been carried over from the infant formula standard without adequate regard for the rationale for its inclusion. In the Codex Infant Formula Standard it states that: *"Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance.*" However, once infants begin consumption of complementary foods there is no reason to continue this restriction. EFSA (EFSA, 2014) commented on this as follows: *"Because complementary food will provide other glycaemic carbohydrates than lactose, there is no reason to restrict their [sucrose and fructose] use in follow-up formula as long as certain maximum levels are not exceeded."* The rationale to exclude fructose for young infants does not extend to young children who are encouraged to consume fruits for example that contain fructose.

Finally, ISDI recommends against inclusion of text relating to non-carbohydrate ingredients added for the purpose of imparting a sweet taste on the basis that:

- While mono- and disaccharides are well defined, the wording "other carbohydrates contributing to the sweet taste" is vague and challenging (aside from the fact that it is somewhat surprising to have a provision on non-carbohydrate ingredients in a section on carbohydrates). Sweetness can be defined relative to sucrose (ESPGHAN, 2017) but sweet taste is influenced by different factors (e.g. genotype or age) (ESPGHAN 2017, Mennella et al 2016) and also food matrix.
- The use of non-carbohydrate ingredients contributing to the sweet taste is already controlled by the absence of permissions as Food Additives in Codex STAN 192-1995, so inclusion or text covering their addition in this proposal is not necessary

References

EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014; 12(7) 3760

ESPGHAN Committee on Nutrition: Sugar in infants, children and adolescents: A position paper of the ESPHAN Committee on Nutrition; JPGN 2017, DOI: 10.1097/MPG0000000000001733

Mennella J,. Bobowski N., Reed D: The development of sweet taste: From biology to hedonics; Rev Endocr Metab Disord 2016 DOI 10.1007/s11154-016-9360-5

Recommendation 6:

ISDI supports this recommendation, with the deletion of the text *"[and other carbohydrates contributing to the sweet taste]".* As per the comment to recommendation 5, ISDI considers this wording to be unprecise.

Recommendations 7 - 8:

ISDI supports these recommendations.

Recommendation 9:

This approach provides a starting basis for discussion in CCNFSDU39.

ISDI questions some aspects of the proposed text and recommends the following amendments to the proposed preamble (highlighted in bold):

> The Codex Alimentarius Commission acknowledges the need to **protect and support** breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where **appropriate**, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods**.** ~~And these products~~ **While these products are not formulated nor intended as substitutes for human milk they** should not discourage **continued** breastfeeding**.**
>
> The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, **as appropriate**, the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. **[~~Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been *endorsed* by member states *may also*~~ provide guidance to countries in this context.]**
>
> This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36

months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Rationale

ISDI takes note that the approach is proposed by the Codex Secretariat, after consultation and discussion with WHO. This practice is unique and unusual in Codex' development of science based standards based on Member States' direction.

ISDI supports the fact that the preamble refers to the consistency of the production, distribution, sale and use of formula with national health and nutrition policies.

ISDI questions the addition of the sentence *"Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / supported] by member states [**may also**] provide guidance to countries in this context."*

As the broader topic of WHO policies and Codex mandate will be considered at the next session of the Codex Alimentarius Commission (CAC41) this addition may prove premature.

If the Committee retains this sentence, reference should be limited to *"Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been **endorsed** by member states **may also** provide guidance to countries in this context."*

Recommendation 10:

ISDI supports this recommendation.

Recommendation 11:

ISDI supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants – and as such would not need to be listed in this high level overview.

Recommendation 12:

In line with the Chair's conclusion, ISDI supports this recommendation and favours the word "shall" instead of "should" as this is more consistent with the terminology used in the labelling section of the Standard.

Recommendation 13:

ISDI does not agree with the first part of recommendation 13 and refers to its comments with regard to Recommendation 9 above. ISDI does not support to add the sentence *"Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / ~~supported~~] by member states [**may also**] provide guidance to countries in this context."*

The broader topic of WHO policies and Codex mandate will be considered at the next session of the Codex Alimentarius Commission (CAC41) to allow for informed discussion and decisions, therefore, ISDI suggests the removal of the sentence in this Codex Standard.

Recommendation 14:

While ISDI supports the text provided in the recommendation for the introductory paragraph to the Labelling section, including a reference to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), ISDI supports that voluntary declarations about the presence or not of nutrients and ingredients (e.g. "low-protein", "lactose free", "contains DHA"), should be permitted on follow-up formula for older infants. ISDI therefore suggests:

- adding the following text in bold to the introductory paragraph to the Labelling Section for follow-up formula for older infants (Section A)

> The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.
>
> **The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to this standard.**

- adding the following two provisions under section 9. Labelling

(New) 9.1 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, Nutrition claims may be permitted for the products that are the subject of Section A of this standard.

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for older infants are adopted by Codex or available at national level.

Rationale

The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) clearly describe what **Nutrient claims** are. They encompass **Nutrient content claims** and **Nutrient comparative claims** as defined below:

2.1 Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

2.1.1 Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: "source of calcium"; "high in fibre and low in fat".)

2.1.2 Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods.(Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

Health claims are a separate category than **Nutrition claims** and are defined in that same Guidelines as "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health", they include:

- Nutrient function claims
- Other function claims
- Reduction of disease risk claims

ISDI supports authorizing Nutrition claims on follow on formula for older infants.

- The valid role of nutrition and health claims has been recognized by national legislation in a number of countries. Nutrition claims such as "low-protein", "lactose free", "contains DHA" are already allowed on labels for foods intended for healthy infants in a number of countries.
- The Global Strategy for Infant and Young Child Feeding states, *"The expert consultation recognized that some mothers will be unable to, or choose not to, follow this recommendation (to breastfeed); they should be supported to optimize their infants' nutrition."* Nutrition claims on formula are a sensible way to encourage optimized nutrition for older infants who are not breast-fed.
- Older infants need nutrient dense foods due to their high needs combined with a limited stomach capacity, but most adult food is not able to provide such density.
- It is crucial that parents and caregivers are able to make appropriate and informed choices about feeding their older infants. Statements about the nutrients and ingredients in the product provide valuable information that helps consumers make these choices.
- Restricting such way of communicating on follow-up formula for older infants would create unequal conditions of competition and could potentially lead to unhealthy food choices for older infants. Furthermore, foods not specifically intended for older infants and young children have to comply with less strict legislation in terms of contaminants, pesticides, hygiene, additives.

ISDI supports the use of nutrition claims for both mandatory and optional nutrients, noting that parents and caregivers are unaware of differences in nutrient categories.

Parents should also be informed of the quantity of daily reference value that is covered by nutrients provided. For this reason, Nutrition Reference Values should be established for this age group.

Recommendation 15:

ISDI does not support this recommendation and instead suggests inserting a reference to NRVs for older infants in the section 5.3.1 as described in ISDI comments on recommendation 14 and which reads:

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for older infants are adopted by Codex or available at national level.

Rationale

ISDI strongly supports the establishment of NRVs-R (*Nutrient Reference Values – Requirements)* for older infants. The establishment of harmonised NRVs-R could inform:

1. Compositional requirements / guide micronutrient composition

This is particularly important for optional nutrients for which compositional requirements (i.e. minimum, maximum, GULs) are not established in Codex standards or national legislation.

2 Nutritional labelling

Where NRVs-R are established, numerical information could be expressed as a % of the NRV-R per 100 g or per 100 ml or per package if the package contains only a single portion. Conveying information regarding the nutrient content of a food on the label enables consumers to make informed nutritional choices.

3 Nutritional Content Claims on food for older infants and young children:

The establishment of NRVs-R for older infants could support the assessment of nutritional claims. The Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) lays down provisions for nutrient content claims based on a minimum % NRV. For example, a 'source' claim could be made for protein if the food meets one of a number of criteria, i.e. 10% of the NRV per 100 g (solids); 5% of NRV per 100 ml (liquids); 5% of NRV per serving etc.

Noting that the work on NRVs for older infants is likely to be a lengthy process, ISDI considers that the revised Standard should include text, similar to the approach taken for protein quality, which makes provision for use of nutrition claims based on NRVs when they become available, rather than the Standard needing to be revisited at this time.

Recommendation 16:

ISDI supports the recommendation for provisions 9.1.1 and 9.1.3.

In provision 9.1.2, ISDI does not consider the addition of the wording "or regional" necessary but is not opposed to it.

In provision 9.1.4 ISDI supports Option1 as it brings clarity. However in 9.1.4 the wording "[protein]" should be removed. It would thus read:

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk ~~[protein].~~

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] ~~[protein]~~. [* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

In provision 9.1.5, ISDI supports the use of the term "may."

Recommendations 17 - 19:

ISDI supports these recommendations.

Recommendation 20:

In section 9.5.6 ISDI is in favour of keeping the sentence *"[is not to be used as a sole source of nutrition]".*

Rationale

ISDI understands the last two provisions of section 9.5.6 have a similar meaning and may be considered redundant. Nevertheless ISDI supports keeping the sentence stating that Follow on formula for older infants "*is not to be used as a sole source of nutrition"* ensures this product is clearly differentiated from Infant Formula. Likewise this would avoid confusion with other products.

Recommendation 21:

ISDI supports most of the recommended wording but strongly opposes the following requirements:

- 9.6.2.2: the sentence *"(including references to milestones and stages)"* should be deleted

- 9.6.2.5: the entire section should be deleted
- 9.6.4: in the last sentence, ISDI questions the relevance of *"in particular as to the text, images and colours used"*

Rationale

In line with the approach taken by the eWG, *"any additional labelling requirements for follow-up formula for older infants should not be more stringent than what is required on the label of infant formula".*

Furthermore, while ISDI supports a clear differentiation between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, ISDI feels that the inclusion of text covering text, images and colours used is very subjective and open to different interpretations.

Recommendation 22:

ISDI supports this recommendation.

Recommendation 23:

ISDI supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants – and as such would not need to be listed in this high level overview

Recommendation 24:

ISDI supports this recommendation and favours the word "shall" instead of "should" as this is more consistent with the terminology used in the labelling section of the Standard.

Recommendation 25:

ISDI does not agree with the first part of recommendation 25 and refers to its comments with regard to Recommendation 9 above. ISDI does not support to add the sentence "*Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / ~~supported~~] by member states [**may also**] provide guidance to countries in this context."*

The broader topic of WHO policies and Codex mandate will be considered at the next session of the Codex Alimentarius Commission (CAC41) to allow for informed discussion and decisions, therefore, ISDI suggests the removal of the sentence in this Codex Standard.

Recommendation 26:

While ISDI supports the text provided in the recommendation for the introductory paragraph to the Labelling section, including a reference to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), ISDI supports that Nutrition and Health claims should be authorized for (Name of Product) for Young Children. Nutrition and Health claims, such as nutrient function claims, should be permitted whenever the nutrient is present at a sufficient amount to achieve the intended effect, and the effect is scientifically substantiated:

ISDI supports the use of both Nutrition and Health claims on nutrients and ingredients permitted for [Name of Product] for Young Children and therefore suggests:

- adding the following text in bold to the introductory paragraph to the Labelling Section for (Name of Product) for Young Children (Section B)

  > The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to (Name of Product) for Young Children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. **The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to this standard.**

- adding the following 2 provisions under section 9. Labelling

  (New) 9.1 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, Nutrition and Health claims may be

permitted for the products that are the subject of Section B of this standard provided, in the case of health claims, that they have been demonstrated in rigorous studies with adequate scientific standards.

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for young children are adopted by Codex or available at national level.

Rationale

The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) clearly describes what Nutrient claims are. They encompass Nutrient content claims and Nutrient comparative claims as defined below:

2.1 Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

2.1.3 Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: “source of calcium”; “high in fibre and low in fat”.)

2.1.4 Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods.(Examples: “reduced”; “less than”; “fewer”; “increased”; “more than”.)

Health claims are a separate category than Nutrition claims and are defined in that same Guidelines as “any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health”, they include:

- Nutrient function claims
- Other function claims
- Reduction of disease risk claims

ISDI supports authorizing both Nutrition and Health claims on (Name of Product) for Young Children.

- The valid role of health and nutrition claims has been recognized by national legislation in a number of countries.
- The Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (Section 3.1 of Codex STAN 146-1985) already lays down detailed instructions to ensure that claims made for the foods are substantiated. Certain health and nutrition claims on labels for foods intended for healthy young children are already allowed in a number of countries.
- The Global Strategy for Infant and Young Child Feeding states, “The expert consultation recognized that some mothers will be unable to, or choose not to, follow this recommendation (to breastfeed); they should be supported to optimize their infants’ nutrition.” Nutrition and health claims on formula are a sensible way to encourage optimized nutrition for young children who are not breast-fed.
- Young children need nutrient dense foods due to their high needs combined with a limited stomach capacity, but most adult food is not able to provide such density. Furthermore, foods not specifically intended for older infants and young children have to comply with less strict legislation in terms of contaminants, pesticides, hygiene, additives.
- It is crucial that parents and caregivers are able to make appropriate and informed choices about feeding their older infants. Caregivers need access to this information and statements about the role of nutrients in the growth and development of young children provide valuable information that helps consumers make informed choices.
- Parents often compare these products with “general” foods that are allowed to use nutrition and health claims but that are not aligned with the Standard. Restricting such way of communicating on products that are specially designed and manufactured for young children would create unequal conditions of competition and could potentially lead to unhealthy food choices for young children. Indeed, [name of the product] for young children is part of a diversified diet of the young children from 1 year of age. At this age, young children consume foods and drinks that parents choose from a variety of foods
- ISDI supports the use of nutrition and health claims for both mandatory and optional nutrients, noting that parents and caregivers are unaware of differences in nutrient categories. Parents should also be

informed of the quantity of daily reference value that is covered by nutrients provided. For this reason, Nutrition Reference Values should be established for this age group.

- Because the composition of (Name of Product) for Young Children is less prescriptive than that of Follow-on formula for older infants previous, there is greater possibility to add optional ingredients. This is important from an innovation perspective and to ensure the best product is available to young children. Therefore, it is important that nutrition and health claims are permitted in order for manufacturers to be able to communicate on the innovations in their products.

For all these reasons ISDI believes it is important that specific provisions for Nutrition and Health Claims are included in this standard.

Recommendation 27:

ISDI does not support this recommendation and instead suggests inserting a reference to NRVs for young children in the section 6.3.1 as described in ISDI comments on recommendation 26 and which reads:

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for young children are adopted by Codex or available at national level.

Rationale

ISDI strongly supports the establishment of NRVs-R (*Nutrient Reference Values – Requirements)* for young children. The establishment of harmonised NRVs-R could inform:

1 Compositional requirements / guide micronutrient composition

This is particularly important for optional nutrients for which compositional requirements (i.e. minimum, maximum, GULs) are not established in Codex standards or national legislation.

2 Nutritional labelling

Where NRVs-R are established, numerical information could be expressed as a % of the NRV-R per 100 g or per 100 ml or per package if the package contains only a single portion. Conveying information regarding the nutrient content of a food on the label enables consumers to make informed nutritional choices.

3 Nutritional Content Claims on food for older infants and young children:

The establishment of NRVs-R for young children could support the assessment of nutritional claims. The Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) lays down provisions for nutrient content claims based on a minimum % NRV. For example, a 'source' claim could be made for protein if the food meets one of a number of criteria, i.e. 10% of the NRV per 100 g (solids); 5% of NRV per 100 ml (liquids); 5% of NRV per serving etc.

Noting that the work on NRVs for young children is likely to be a lengthy process, ISDI considers that the revised Standard should include text, similar to the approach taken for protein quality, which makes provision for use of nutrition claims based on NRVs when they become available, rather than the Standard needing to be revisited at this time.

Recommendation 28:

ISDI supports the recommendation for provisions 9.1.1 and 9.1.3. In provision 9.1.2, ISDI does not consider the addition of the wording "or regional" necessary but is not opposed to it.

In provision 9.1.4 ISDI supports Option1 as it brings clarity. However in 9.1.4 the wording "[protein]" should be removed. It would thus read:

9.1.4(a) If [name of animal] milk is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk ~~[protein].~~

9.1.4(b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] ~~[protein]~~. [* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

In provision 9.1.5, ISDI supports the use of the term "may."

Recommendations 29 - 32:

ISDI supports these recommendations.

Recommendation 33:

In previous comments, ISDI asked that the following sentence be added as per the current Follow-up Formula Standard in section 9.6 Additional Requirements: "*The products covered by this standard are not breast-milk substitutes and shall not be presented as such."*

ISDI recommends to expand section 9.6.2 to read as follows:

> [9.6.2] [**The products covered by this standard are not breast-milk substitutes and shall not be presented as such.**] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used].

ISDI would nevertheless request the CCNFSDU to reinstate the provision that (name of product) for young children is not a breastmilk substitute (or, if it is preferred to avoid use of this term, not a substitute for human milk) in provisions detailed in 9.6 of Section B of the revised standard. There was a strong support within the eWG that [name of product] for young children are not breastmilk substitutes.

(Name of product) for young children is not developed to be able to satisfy by itself the nutritional needs of a young child but to address recognised potential diet inadequacies.

Recommendation 34:

ISDI supports this recommendation.

Recommendation 35:

ISDI does not support the addition of the last sentence and suggests deleting it. The definition would then read:

> (Name of Product) for young children means a product specifically formulated and manufactured intended for use as a liquid part of a progressively diversified diet in order to contribute to the nutritional needs of young children. ~~[when nutrient intakes may not be adequate to meet nutritional requirements]~~

Rationale

ISDI supports the addition of the word "*formulated"* in the definition as it clarifies that the product is the result of specific and voluntary effort of the manufacturer to prepare a product for a specific intended use. Formulation refers to the phase of theoretical development of the product preceding the manufacturing itself (e.g. choice of specific ingredients when developing the product recipe).

With regards to the sentence *"when nutrient intakes may not be adequate to meet nutritional requirements",* ISDI supports it should not be inserted as it could lead to the interpretation that a progressively diversified diet may not be sufficient to meet the nutritional requirements of young children or that the product can be used only when nutrient intakes are not adequate.

Recommendation 36:

ISDI supports this recommendation.

Recommendation 37:

ISDI supports both proposed names in English and recommends the Committee to consider faithful translation in other languages.

UNICEF

Recommendation 9 – Proposed Approach

UNICEF disagrees with the proposed approach. Although the draft mentions specific reference to relevant WHO documents and WHA resolutions, the proposed wording does not provide the necessary detail in terms of the specific documents and resolutions that need to be referenced.

UNICEF feels strongly that resolutions WHA 39.28, WHA 63.23 and WHA 69.9 must be referenced, and that the discussion on this approach and wording must be reopened at the upcoming CCNFSDU meeting as concluded at the 38th CCNFSDU session.

Recommendation 13 – Section 1.4

UNICEF strongly supports the inclusion of a reference to the specific WHA Resolutions (WHA 39.28, WHA 63.23 and WHA 69.9) in this standard, and thus cannot support recommendation 13 in section 1.4 unless the

Preamble text includes explicit reference to those resolutions. If the Resolutions are not included in the Preamble, then provision 1.4 must not be deleted and must refer to WHA 39.28, WHA 63.23 and WHA 69.9.

Recommendation 25 – Section 1.4

UNICEF does not support this recommendation unless the Preamble text includes explicit reference to those resolutions. If the Resolutions are not included in the Preamble then provision 1.4 must not be deleted and must refer to WHA 39.28, WHA 63.23 and WHA 69.9.

Recommendation 33 – Additional Labelling Requirements

UNICEF still believes that option 1 omits many of the labelling requirements that are necessary to avoid confusion and the use of the label to promote or idealize the product and undermine breastfeeding, considering that this product has been identified by WHO as a breastmilk substitute. There was no clear consensus on this issue and Option 2 should still be considered in the discussions at the upcoming meeting.

Recommendation 34

UNICEF would like to remind the CCNFSDU Committee members that it is called upon by the World Health Assembly to give full consideration to WHO guidance and recommendations, including the International Code of Marketing of Breast-milk substitutes and relevant World Health Assembly Resolutions. It must take into account the fact that WHO has recommended that the product under consideration be considered a *breastmilk substitute* and that the Assembly has called on Governments to implement that recommendation. This, combined with the fact that there has been no real consensus in the electronic working group on the definition, leads UNICEF to recommend that the following definition be included for discussion, ensuring that it is clear to policy makers, manufacturers and the consumer that this is a breastmilk substitute:

> "Follow-up formula for older infants means a product, specially manufactured for use as a substitute for breast-milk as a liquid part of the diet for older infants when complementary feeding is introduced."

Recommendation 35

UNICEF would again like to remind the CCNFSDU Committee that it is called upon by the World Health Assembly to give full consideration to WHO guidance and recommendations, including the International Code of Marketing of Breast-milk substitutes and relevant World Health Assembly Resolutions. It must take into account the fact that WHO has recommended that the product under consideration be considered a breastmilk substitute and that the Assembly has called on Governments to implement that recommendation. Since there was no consensus on any one definition in the eWG, UNICEF proposes that the following definition be included for consideration at the upcoming meeting:

> Name of Product: for young children means a product specially manufactured for use as a substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a liquid part of the progressively diversified diet.

Recommendation 37

As stated in the last submission to the eWG, UNICEF believes that the use of the word "formulated", conveys a promotional message and may lead to the idealization of the product in the minds of consumers.

Given that UNICEF had proposed the name "Young child milk-based (or plant-based) drink.", but that it is now proposed that the source of protein in relation to the name of the product be covered within Section 9.1 as a separate labelling provision, UNICEF recommends the use of the name Young child drink".