CODEX ALIMENTARIUS COMMISSION

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.2**

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

Thirty-ninth Session

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4 – 8 December 2017

REVIEW OF THE STANDARD FOR FOLLOW-UP-FORMULA (CODEX STAN 156-1987)

Comments of Australia, Canada, Kenya, Malaysia, Norway, Philippines, Tanzania, Thailand, European Food Law Association (EFLA), International Council of Grocery Manufacturer Associations (ICGMA), International Special Dietary Foods Industries (ISDI)

AUSTRALIA

1.1 Structure and name of the Standard

Australia notes the comments that the final structure and name of the standard are still outstanding and because of this we believe there are likely implications for the outcomes on some of the recommendations. For example discussion on Recommendation 9 relating to the preamble could potentially be more focused subject to agreement on the final structure i.e. whether both products are retained within one Standard.

Comments on specific recommendations

Recommendation 1: Protein minimum in formula for older infants

Australia does not support the proposed minimum protein level for non-hydrolysed cow and goat milk protein and the associated footnote as currently drafted. We are concerned the proposed drafting is unclear and potentially confusing in the global context.

We note the comment that the 2017 EFSA Scientific Opinion is relevant to '*healthy infants living in Europe with an intake of complementary foods of a sufficient quality and cannot be generalised to countries where protein intakes may be lower and/or of poorer quality*' and as such, unconditional acceptance of lower protein does not seem warranted. This point was also discussed at CCNFSDU38 highlighting that the standard needed to take into account the global diversity of protein intakes and quality in this age group. Thus, consideration needs to be given to the drafting applying in those countries where protein intakes may be lower and/or of poorer quality. On this basis, it is inappropriate to establish a minimum level which may not be suitable for all countries and that requires competent national and/or regional authorities to evaluate the evidence to determine if the global standard minimum is appropriate.

We also recognise the footnote is critical to the operation of the minimum protein level and are concerned that if expressed as currently proposed the footnote could be overlooked or ignored.

Therefore Australia's preference is to set the minimum protein level at 1.8 g/100 kcal and allow flexibility for the 1.6 g/100 kcal through the footnote. The footnote would allow protein minimum levels between 1.6 – 1.8 g/100 kcal to be established as safe and suitable for infants following scientific evaluation by competent national and/or regional authorities in the context of the nutritional needs of their local population. This approach still enables countries to consider whether to permit protein levels below 1.8 g/ 100 kcal based on their own scientific evaluation of the evidence.

Based on Australia's comment above the proposed changes are provided below with bolded insertions and strike through text

a) Protein [2), 3), 4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	~~[1.6]~~ **1.8**[5),6)]	3.0	-

g/100 kJ	~~[0.38]~~ **0.43**[5),6)]	0.72	-

6) Follow-up formula based on non-hydrolysed milk protein containing **1.6 - <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** evaluated for its safety and suitability **in the context of the nutritional needs of the local population** by a competent national and/or regional authority.

Recommendations 4, 5 and 6: Carbohydrate in [name of product] for young children

Overall, Australia supports the three-pronged approach to managing the amount and types of carbohydrates used in [name of product] for young children however we have comments specific to each of the individual recommendations as follows.

Recommendation 4: Maximum level of available carbohydrate

Australia does not support a maximum of 12.5 g/100 kcal of available carbohydrate. Australia re-iterates support for a maximum level of available carbohydrate of 14 g/100kcal. We do not consider that there is an associated health risk with the higher maximum level of 14 g/100 kcal in the diets of some young children.

As previously agreed by the eWG ensuring the nutritional balance of the product is important thus the macronutrients must not be considered in isolation. Lowering the carbohydrate level has implications for the fat and protein levels. As the *NDFSDU 38 PWG Side Session report: Modelling Macronutrient Levels (CRD17)* determined: the higher level (14 g/100kcal) achieves nutritionally balanced composition for [name of product] for young children; and enables flexibility as products can be formulated either as low protein or low fat (but not both).

In addition the higher level of 14 g/100 kcal of available carbohydrate:

- Meets all of the objectives of the eWG
- Aligns with the approach taken to set the maximum carbohydrate level in the revised requirements for follow-up formula for older infants (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 (difference of 0.3 g/100 kcal between maximum levels of carbohydrates of 12.5 or 14 g/100 kcal).

Recommendation 5: Sugars, other than lactose, and other sweet tasting carbohydrates

Australia supports the recommendation to establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates and to use the definition of sugars from CAC/GL 2-185: i.e. 'mono- and disaccharides' instead of 'sugars'. We also support the amended footnote 4 and limiting the addition of ingredients with a sweet taste, is addressed by limiting added sugars (excluding lactose) and indicating that lactose is the preferred carbohydrate.

Recommendation 6: Conversion of % limits to an absolute amount

Australia supports recommendation that the percentage limit for sugars 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.

Expressing the sugars limits as absolute amounts e.g. x g /100 kcal, rather than as a percentage of the maximum available carbohydrate sets a maximum amount for all products irrespective of the amount of carbohydrate in the product. We assume that the conversion would be based on the agreed percentage of the agreed maximum available carbohydrate, for example, 20% of 14 g/100 kcal = 2.8 g/100 kcal.

Recommendation 9: Inclusion of Preamble statement

Australia notes the range of views in regards to this matter, and recognises there is precedence for including a Preamble given the now independent albeit dated document 'Statement on Infant Feeding' (CAC/MISC2-1976).

Australia therefore supports the inclusion of the proposed Preamble statement in the Standard with the exception of the last paragraph as we consider this text is more appropriately placed within the Scope section which is the appropriate place to include the names of the products covered by the Standard. Although we note the appropriate placement of this paragraph will likely depend on the decision in regard to the outstanding issue on the Structure and Name of the standard (see above comment on 1.1)

Additionally as indicated above in our comment on 1.1, we recognise that the outstanding decision on the final structure of the Standard has potential implications for the inclusion of a Preamble as well as its final wording. Australia is therefore exploring whether there is another approach to address the necessity and/or nature of the Preamble including whether the 'Statement on Infant Feeding' (CAC/MISC2-1976) should be revised or rescinded.

Australia's preferred wording for the Preamble is indicated with strikethrough text below with one additional insertion in underlined bold.

> *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* ***<u>older</u>*** *infants provided ~~they~~* ***these formulae*** *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**s** ~~(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 32: Information for Use

In general Australia supports the recommendation in relation to Section 9.5 but has comments on 9.5.3 and a minor editorial correction to 9.5.4.

Australia has previously expressed the view that (name of product) for young children is more like a cow's milk replacement which is reflected in the less prescriptive compositional requirements. Therefore consistent with this view, we do not consider requiring graphic instructions on the method of preparation to be necessary given the inclusion of 'illustrating' and propose the following deletion as indicated with strikethrough to 9.5.3. We also suggest deletion of 'and' in 9.5.4 to correct an editorial error as follows.

> **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 ~~and~~ about the health hazards of inappropriate preparation, storage and use**.**

Recommendation 35 - Product definition (Name of product) for young children

Australia considers *(Name of product) for young children* to be supplementary in nature and therefore in general support the intent of the proposed definition. However to ensure the supplementary nature of the product is captured we prefer use of **'***when nutrient intakes may not be adequate to meet nutritional requirements'*. We also consider 'progressively' and 'diversified' are not necessary and that the sentence *'in order to contribute to the nutritional needs of young children'* may imply that the product would be necessary for meeting the nutritional needs of all young children.

Our preferred definition as amended is:

> *(Name of Product) for young children means a product specially [formulated and] manufactured for use as a liquid part of the diet of young children when nutrient intakes are not likely to be adequate to meet nutritional requirements.*

Recommendation 37: Name of the product

Australia does not support either of the proposed names. We reiterate our support to include 'Supplementary' in the name as it reflects the role of the product in the diet of young children as they are not necessary but can be beneficial in contributing to the nutritional needs of young children when nutrient intakes may not be adequate.

Australia has always regarded these products as supplementary rather than as a substitute for formula that is suitable for younger age groups and would prefer that this is made clear in the Codex name for these products. We therefore propose '**Formulated supplementary drink for young children'**

CANADA

General Comments

Canada thanks New Zealand, France and Indonesia for chairing the eWG and for their extensive work in preparing the agenda paper and recommendations for the revision of the follow-up formula standard, for consideration by the Committee.

Specific Comments:

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

1.5 Protein

Recommendation 1:

Canada does not agree with Recommendation 1, point 1, that a minimum protein level of 1.6 g/100 kcal is established. Canada would prefer that the minimum protein level be 1.8 g/100 kcal, to allow for the use of the standard world-wide. We note that the EFSA recommendation of 1.6 g/100 kcal was for the population in Europe, where older infants are likely to be consuming a diverse diet with a variety of protein containing foods. A global standard should be appropriate to all populations, and provide safe formulas with sufficient protein content. However, we agree that a footnote should be added to allow for more flexibility in the minimum protein content for countries that may have different regional needs.

Canada agrees with points 2 to 4, and the proposed text.

Canada agrees with footnote 2, and notes that no conversion factor is provided for soy based formulas.

Canada agrees with footnotes 3 and 4. Canada agrees that in footnote 5 **non-goats'** should be included in the second sentence. The bracket for the minimum value of [2.25 g/100 kcal (0.54 g/100 kJ)] should be included. Canada agrees with footnote 6.

Recommendation 2:

Canada agrees with this GUL and does not object to the minimum of 13 mg/100 kcal.

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

2.4 Minimum total fat

Recommendation 3:

Canada agrees to a minimum of 3.5 g/100 kcal for fat. This is consistent with the fat content of reduced fat milk (2%).

2.5 Carbohydrate

Recommendation 4:

Canada agrees to a maximum of 12.5 g/100 kcal for available carbohydrates.

2.6 Sugars, other than lactose, and other sweet tasting carbohydrates

Recommendation 5:

Canada agrees with recommendation 5.

2.6.4 Conversion of % limits to an absolute amount based on the energy density

Recommendation 6:

Canada agrees with Recommendation 6.

2.7 Calcium-to-phosphorous ratio

Recommendation 7:

Canada does not have any objection to recommendation 7, given that phosphorus is present in the diets of young children and is not a nutrient of public health concern.

2.8 Vitamin D

Recommendation 8:

Canada agrees with Recommendation 8.

3 PREAMBLE

3.3 Proposed approach

Recommendation 9:

Canada agrees with the Chair's proposals. We prefer the wording **[protect and support]** in the first bracket, to be consistent with the wording in WHO documents, and **[appropriate]** in the second bracket. The wording **[as appropriate,]** in the third bracket should be deleted. The use of the word**, [supported]** should be used **in the fourth bracket** as not all resolutions are endorsed. Finally the words **[may also]** should be deleted, as this wording is not needed.

As we are aware that several member countries support the listing of relevant WHO and WHA documents, a footnote at the end of the 2nd paragraph could be added as a compromise. The wording 'and future relevant resolutions' could be added at the end of this paragraph.

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

5.2 Scope – Individual Provisions

5.2.1 Scope – Section 1.1

Recommendation 10:

Canada agrees with recommendation 10.

5.2.2 Scope – Section 1.2

Recommendation 11:

Canada agrees with Recommendation 11.

5.2.3 Scope – Section 1.3

Recommendation 12:

Canada agrees with Recommendation 12, with the use of the word **[should]**.

5.2.4 Scope – Section 1.4

Recommendation 13:

Canada agrees with Recommendation 13.

5.3 Labelling – Introductory Paragraph

5.3.1 Ingredient and nutrient declarations/claims

Recommendation 14:

Canada agrees with Recommendation 14.

5.3.2 Nutrient Reference Values (NRVs) for infants and young children

Recommendation 15:

Canada agrees with Recommendation 15.

5.4 Labelling - Name of the Product

Recommendation 16:

Canada agrees with 9.1.1 to 9.1.3, and to remove the brackets around **"or regional".** Canada prefers Option 2 for 9.1.4 because it would already be allowed under 9.1.3. If Option 1 is retained, we suggest **deletion of the word [protein] that is currently in brackets in 9.1.4(a), and 9.1.4(b).**

Canada supports 9.1.5.

5.5 Labelling - List of Ingredients

Recommendation 17:

Canada agrees with the revised 9.2.1 as this ensures labelling consistency with the standard for infant formula. Canada proposes that under 9.2.2., the last sentence be re-phrased to **'The food additive INS number may also be optionally declared'**.

5.6 Labelling – Declaration of Nutritive Value

Recommendation 18:

Canada agrees with Recommendation 18.

5.7 Labelling – Date Marking and Storage Instructions

Recommendation 19:

Canada agrees with recommendation 19.

5.8 Labelling – Information for Use

Recommendation 20:

Canada agrees with Recommendation 20, with some changes in wording in 9.5.1, for the purposes of clarity.

9.5.1 [Ready to use] products in liquid form **[~~may~~] [should]** be used **[~~either~~]** directly. **[~~or~~] [~~in the case of~~]** [**C** ~~**c**~~]oncentrated 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.

5.9 Labelling – Additional Labelling Requirements

Recommendation 21:

Canada agrees with 9.6.1 to 9.6.3. For [9.6.4] we propose the following: '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.~~]'. It is best left to national authorities to determine the most appropriate way to communicate these distinctions.

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

6.2 Scope – Individual provisions

6.2.1 Scope – Section 1.1

Recommendation 22:

Canada agrees with Recommendation 22.

6.2.2 Scope – Section 1.2

Recommendation 23:

Canada agrees with Recommendation 23.

6.2.3 Scope – Section 1.3

Recommendation 24:

Canada agrees with Recommendation 24 with the use of the word [**should]**.

6.2.4 Scope – Section 1.4

Recommendation 25:

Canada agrees with Recommendation 25.

6.3 Labelling – Introductory Paragraph

6.3.1 Ingredient and nutrient declarations/claims

Recommendation 26:

Canada agrees with Recommendation 26.

6.3.2 Nutrient Reference Values (NRVs) for infant and young children

Recommendation 27:

Canada agrees with Recommendation 27.

6.4 Labelling – Name of the Product

Recommendation 28:

Canada agrees with 9.1.1 to 9.1.3., and to remove the brackets around “or regional”. Canada prefers Option 2 for 9.1.4 because it would already be allowed under 9.1.3. If Option 1 is retained, we suggest deletion of the word [protein] that is currently in brackets in 9.1.4(a), and 9.1.4(b). Canada supports 9.1.5.

6.5 Labelling – List of Ingredients

Recommendation 29:

Canada agrees with Recommendation 29 with the last sentence re-phrased to **‘The food additive INS number may also be optionally declared’.**

6.6 Labelling – Declaration of Nutritive Value

Recommendation 30:

Canada agrees with Recommendation 30.

6.7 Labelling – Date Marking and Storage Instructions

Recommendation 31:

Canada agrees Recommendation 31.

6.8 Labelling – Information for Use

Recommendation 32:

Canada agrees with 9.5.1, but with some changes in the wording, for the purposes of clarity:

9.5.1 [Ready to use] products in liquid form [**~~may~~**] [**should**] be used **[~~either~~**] directly. [~~or] [in the case of~~] [**C** ~~c~~]oncentrated 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.

Canada proposes to delete 9.5.4 and 9.5.5 as the information is covered in 9.5.1 and 9.5.2, and as this product is for younger children, the consumption is likely to be lower.

Canada agrees with 9.5.6.

6.9 Labelling – Additional Labelling Requirements

Recommendation 33:

Canada agrees to Recommendation 33, with the deletion of **[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used**] in 9.6.2. It is best left to national authorities to determine the most appropriate way to communicate these distinctions.

7 DEFINITIONS

7.1 Product definition – follow-up formula for older infants

Recommendation 34:

Canada agrees with Recommendation 34.

7.2 Product definition – [Name of product] for young children

Recommendation 35:

Canada supports the following wording:

“[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]**.”

The wording ‘specially formulated’ would imply a specific need for the product, and the wording ‘in order to contribute to the nutritional needs of young children’ also implies that the product is necessary, so should be deleted.

8 NAME OF PRODUCTS

8.1 Name of product for older infants

Recommendation 36:

Canada agrees with Recommendation 36.

8.2 Name of product for young children

Recommendation 37:

Canada prefers '**Formulated drink for young children**'. This wording is structurally similar to 'Follow-up formula for older infants'.

KENYA

Kenya would like to comment the electronic group led by New Zealand, France and Indonesia for guiding in the work of this agenda item.

Our comments to the recommendations are as follow:

Recommendation 1: setting a minimum protein level of 1.6 g/100 kcal

Comment: We do support lowering the protein minimum to 1.6 g/100Kcal. We propose we maintain 1.8 g/100Kcal

We also support to maintain footnote 6 as recommended by EWG.

Justification:

1. Based on practices in using these formulas, over dilution is a common occurrence due to social-economic status and thus children consume less volume.
2. The available alternative sources of protein are poor and thus based on the EFSA Opinion the recommendation to lower the protein will not applicable to our case.
3. In resource constraints countries the burden of protein-energy deficiency is still high.

Recommendation 2: A minimum in the footnote for the optional addition of docosahexaenoic acid is set to 13 mg/100kcal (3.1 mg/100 kJ) and a GUL (Guided Upper Limit) of 0.5% of total fatty acids is converted to 30 mg/100 kcal (7.9 mg/100 kJ).

Comment: We support the recommendation as proposed

Justification: DHA is a component of breast milk and it has important physiological role in the development of infants and young children. The proposed level is comparable to that found in breast milk.

Recommendation 3: Setting the minimum level for fat of 3.5 g /100 kcal (0.84 g/100 kJ).

Comment: We do not support setting a minimum of 3.5 g/100 Kcal.

Justification: It is recommended that fat should contribute about 30 – 35 % of the energy for this age group. Given the increased activity and growth, the population will require more energy for both maintenance and growth. We therefore propose that a minimum of 4 g/Kcal be established for this product.

Recommendation 4: Setting a maximum level for available carbohydrates of 12.5 g/100 kcal (3.0 g/100kJ).

Comment: We agree with the recommendation.

Justification: The proposed level will provide sufficient energy from carbohydrates in the product.

Recommendation 5: That

a) Establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates.

b) Sweet tasting carbohydrates are restricted in accordance with the amended footnote 4 below.

c) Consider the need to limit the addition of non-carbohydrate ingredients with the purpose of imparting a sweet taste.

Comment: We support the recommendation.

Justification: Simple sugars are known to influence the test preferences of the infants and young children thus if they are limited to the proposed level will ensure that the technological function is achieved without affecting the test preferences of the children and infants.

Recommendation 6: 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.

Comment: We support the recommendation

Justification: It will help determine the amount of energy contributed by the specific carbohydrates in the product.

Recommendation 7: Not to establish calcium-to-phosphorous ratio is included for [name of product] for young children.

Comment: There is need to establish the Ca:P ratio

Justification: The national demographic health surveys have shown 1 in 5 children are not appropriately weaned and thus are not able to benefit in the diversified diet. Therefore, this product should be formulated in a way that if mother choose the product it should provide nourishment to their children. In addition, those who use these products believe that they are formulated to provide better nourishment to their children.

Recommendation 8: Mandatory addition of vitamin D and minimum and maximum levels

Comment: We do not support.

Justification: The cases of Vitamin D deficiency manifested by rickets in gradually increasing even in countries with sufficient sun exposure

Recommendation 9: That

CCNFSDU agree to the approach proposed by the Codex Secretariat and WHO, that being to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA resolutions.

That CCNFSDU agree to the following Preamble statement proposed by the Codex Secretariat and WHO, and select the preferred wording from that presented in square brackets:

Comment: We support the introduction of a preamble with the following amendment to the text.

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 WHA resolutions 39.28, 63.23, 69.6 and any 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).

Justification: This it to ensure that the principle of protecting, promoting and supporting breast feeding as intended by the International code and its accompanying resolution is hungered in these products not as option but as a mandatory requirements. Our national legislation (BMS –Control and regulation – Act of 2012) includes follow-up formula under its control so as to ensure breast feeding continues up to 2 years and beyond.

Recommendation 10: That CCNFSDU agree to the following statement for Section 1.1:

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.

Comment: We support the proposed text.

Recommendation 11: 1.2 This section of the Standard contains compositional, quality, safety, ~~[~~labelling and analytical~~]~~ requirements for Follow-up Formula for Older Infants.

Comment: We support the proposed text

Recommendation 12: That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

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.

Comment: We support the use of the term 'Shall' but not "should" in the statement

Rationale: The use of '**shall**' makes it mandatory for the products to comply as opposed to 'should'.

Recommendation 13: That CCNFSDU agree to:

- 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.

- delete provision 1.4 for follow-up formula for older infants from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.

Comment: We can support the recommendation subject to the comments in recommendation 9.

Justification: Including the issue of WHA in the preamble of the two section will serve the same purpose as when included in the scope.

Recommendation 14: Introductory paragraph to the Labelling Section for follow-up formula for older infants (Section A):

Comment: We support the drafting and emphasis on nutrition and health claims. We note as much as the paragraph alludes that claims may be made if allowed by the relevant codex standard, all the five current standards for products for infants and young children prohibit the claims.

Justification: Nutrition and health claims are not allowed in all products to be consumed by infants and young children. This revision should not introduce these claims as they have the potential of negatively affecting the introduction of nutritious complementary feeding

Recommendation 15: A decision on the need to revisit nutrition claims on the completion of NRVs for infants and young children is not required by CCNFSDU at this point in time.

Comment: Establishment of NRV should not hold the review of this standard

Justification: Since the establishment of the NRV has not even started, holding the revision of this standard to wait for the NRVs will result to unnecessary delay.

Recommendation 16: OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

Comment: We support option 2 on deletion of 9.1.4

Justification: Clause 9.1.3 satisfactory addresses the issue of protein declaration.

Recommendation 17: 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. ~~[~~The INS number of Food additives may also optionally be declared.~~]~~.

Comment: We support the recommendation

Justification: Providing the name and INS numbers is important in identifying the specific food additives used.

Recommendation 18: 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.

Comment: We support the proposed text

Recommendation 19: As this paper was written prior to CCFL44, it is recommended that CCNFSDU agree to modify the above text (as necessary) and adopt any changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017.

Comment: We agree with the proposed text

Justification: This advice is based on the procedural manual where committee refers matters to the competent committee for advice.

Recommendation 20: That CCNFSDU agree to the following text for Section 9.5 and consider the proposed rewording of provision 9.5.1

Comment: We agree with the proposed text

Rationale: The proposed text will ensure good hygienic practices during preparation of the product and thus protect the consumers.

Recommendation 21: [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**.]

Comment: We support the recommendation and open brackets in 9.6.4

Justification: This will ensure consumers do not confuse products due to similarity of labels/colours for the various products.

Recommendation 22: That CCNFSDU agree to the following statement for Section 1.1:

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.

Comment: Acceptable as drafted

Recommendations 23 - 33: Similar wording for section 2 as was in section 1:

Comment: Comment given in similar recommendation under section 1 applies.

Recommendation 34: Definition: 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~~ **as a part of complementary feeding.**

Comment: We support the definition with amendment as highlighted

Justification: The definition of complementary food includes any other food/drink given to an infant other than breast milk.

Recommendation 35: Definition for young children: [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].

Comment: We do not support the proposed. Instead we propose as follows:

[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.

Justification: The proposed definition is consistent with definition of follow up formula for older infants, the difference being the age.

Recommendation 36: That the name Follow-up Formula for Older Infants be adopted as the name of product for the 6 – 12 month age group (older infants).

Comment: We agree with proposed name – follow-up formula for older infants

Justification: For consistency in naming food products for use by the infant

Recommendation 37: That the following two names for product for young children.

- Formulated drink for young children
- Young child formulated drink

Comment: We support 'Formulated drink for young children'

Justification: The word 'formulated' will distinguish this drink with other drinks available in the market such as fruit drinks.

MALAYSIA

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

Recommendation 1: Minimum protein

Malaysia supports the minimum protein level of 1.6 g/100 kcal and that clinical evaluation is required for formula with protein levels below 1.8 g/100 kcal.

However, Malaysia would like to propose to delete the statement "by a competent national and/or regional authority" in footnote 6 because conducting clinical evaluation is the responsibility of the manufacturer and competent national authorities should not be burdened with this task, although the latter will review the data provided by the manufacturer.

Recommendation 2: Optional addition DHA

Malaysia agrees with recommendation 2 and proposes to remove square brackets.

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

Recommendation 3: Minimum total fat

Malaysia agrees with the proposal to establish a minimum level for fat of 3.5g/100 kcal (0.84 g/100 kJ).

Recommendation 4: Maximum level available carbohydrate

Malaysia supports the maximum level for available carbohydrates of 14.0 g/100 kcal.

Based on a macronutrient modelling that has been carried out (see below), it is demonstrated that all products formulated with a carbohydrate level of 14 g/100 kcal is nutritionally the most preferred as it fits into the Acceptable Macronutrient Distribution Range (AMDR) of international recommendations for the macronutrients (FAO/WHO 2002 & 2010, FAO/WHO/UNU, 2007, EFSA, 2013; IoM, 2002; Suthutvoravut et al, 2015).

The justification and explanation as follow:

Below is 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. The comparison is made using carbohydrate maximums levels at 12.5 and 14 g/100 kcal.

Table 1 shows that if the maximum carbohydrate level is 12.5 g/100 kcal and the minimum protein is 1.8 g/100 kcal as indicated for Product 1, the resulting fat level would be 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 as indicated for Product 3, the resulting protein level would be 4.6 g/100 kcal (18.5% of energy).

Both these 2 scenarios (Product 1 and 3) 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.

On the other hand, if the modelling is carried out using maximum carbohydrate level at 14 g/100 kcal, the resulting fat and protein meet international recommendations, as summarised below.

Table 1 shows that if the maximum carbohydrate level is at 14 g/100 kcal and the minimum protein is 1.8 g/100 kcal as in Product 2, the resulting fat level would be at 4.1 g/100 kcal (36.8% energy).

Similarly, product 4 in Table 2 shows that if the maximum carbohydrate level is at 14 g/100 kcal and the minimum fat is at 3.5 g/100 kcal, the resulting protein level should be at 3.1 g/100 kcal (12.5% energy).

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

The results of the above modelling can be summarised in Table 3, compared with the Acceptable Macronutrient Distribution Range (AMDR) of international recommendations. The table shows clearly that products 2 and 4 formulated with a carbohydrate level of 14 g/100 kcal is nutritionally the most suited to the Acceptable Macronutrient Distribution Range (AMDR) of international recommendations while maintaining the nutritional integrity.

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 [1]**	**IoM[2]**	**FAO /WHO**	**ENA[3]**
CHO	50	50	56	56	45-60	45-65	55-75[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

[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.

Recommendation 5: Sugars, other than lactose, and other sweet tasting carbohydrates

Malaysia agrees to the proposed statement in the footnote 4 and proposes to remove all the square brackets as follows:

> 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.]**

Recommendation 6: Conversion of % limits to an absolute amount based on the energy density

Malaysia agrees that limits should be presented as total energy density (g/100 kcal and g/100 kJ) of product.

Recommendation 7: Calcium – to-phosphorous ratio

Malaysia agrees with the recommendation 7.

Recommendation 8: Vitamin D

Malaysia agrees to the proposed minimum level for vitamin D of 1.5µg/100 kcal. However, Malaysia is of the view that the maximum level of Vitamin D should not be set. Available data shows that the Vitamin D deficiency is still a public health concern in Malaysia. Furthermore, excessive addition may not be a concern as the level of addition is self limiting in a way.

Recommendation 9: PREAMBLE

Malaysia would like to reiterate its previous position there should be 2 separate standards for each product category with a point differentiation at 12 months, ie one standard for older infants of age 6-12 months and another standard for young children from 12-36 months. The names of the two product categories standard have also been previously proposed by Malaysia, ie

i) Follow-up Formula

ii) Formulated Milk Powder (or soy-based) product for Young Children or other similar terminology

As such, Malaysia is of the opinion that the current text proposed in the 3 paragraphs in italics should be re-written as appropriate for the 2 separate standards products categories and are more relevant to be in the Scope of the standard. This approach would be in line with format of the current standards for Infant Formulas and Formulas for Special Medical Purposes (CODEX STAN 72-1981).

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

Recommendation 10: SCOPE

Malaysia supports the proposed statement in section 1.1.

Recommendation 11: SCOPE

Malaysia does not agree the word “analytical” because this term generally refers to laboratory requirements for the analysis of essential composition, quality and safety, for which there is a specific section on “methods of analysis and sampling” and as such do not need to be included in this section of the standard. This would be in line with the current Codex Standard for Infant Formula (CODEX STAN 72 – 1981) where analytical is not mentioned in the scope of the product. Therefore, section 1.2 to read as follows:

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

Recommendation 12:

Malaysia agrees to the proposed statement in paragraph 1.3 and the word “should” is more appropriate. The statement would be:

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard should be presented as Follow-up-Formula for older infants.

Recommendation 13: WHO documents and WHA resolutions

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Recommendation 14: Labelling

Malaysia agrees with the recommendation 14.

Recommendation 15: NRV

Malaysia has no objection to the recommendation as proposed.

Recommendation 16: Name of product

Malaysia agrees with option 2.

Recommendation 17: List of ingredients

Malaysia does not agree that specific name for food additive should be declared as it is not in line with the requirement in national legislation. Under Malaysia Food Regulations 1985, the functional class of food additive and INS number should be declared.

Recommendation 18: Declarative of nutritive value

Malaysia agrees with the proposed drafting text for older infants in paragraph 9.3 (a), (b) and (c).

Recommendation 19: Date marking and storage instructions

Malaysia proposes to follow the development on the date marking requirement that is currently been discussed in CCFL.

Recommendation 20: Information for use

Malaysia is of the opinion that the statement in paragraph 9.5.6 i.e “is not to be used as a sole source of nutrition” is still important under the information for use, therefore should not be deleted.

Recommendation 21: Additional Labelling requirements

Malaysia would like to propose to delete the words “(including references to milestones and stages)” in paragraph 9.6.2.2.

However, Malaysia supports the words “and to enable consumers to make clear distinction between them” in paragraph 9.6.4 but proposes to delete the words “in particular as to the text, images and colours used”. Therefore, the sentence should be read as follows:

- **[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: SCOPE

Malaysia supports the proposed statement in section 1.1.

Recommendation 23:SCOPE

Malaysia does not support the word “analytical” because the term generally refers to laboratory requirements for the analysis of essential composition, quality and safety, for which there is a specific section on “methods of analysis and sampling” and as such do not need to be included in this section of the standard. This would be in line with the current Codex Standard for Infant Formula (CODEX STAN 72 – 1981) where the analytical requirements are not mentioned in the scope. Therefore, section 1.2 to read as follows:

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

Recommendation 24: SCOPE

Malaysia agrees to the proposed statement in paragraph 1.3. and the word “should” is more appropriate. The statement would be:

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

Recommendation 25: WHO AND WHA

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Recommendation 26: Labelling-introductory

Malaysia agrees with the recommendation 26.

Recommendation 27: NRV

Malaysia has no objection to the recommendation as proposed.

Recommendation 28: Name of product

Malaysia agrees with option 2.

Recommendation 29: List of ingredients

Malaysia does not agree that specific name for food additive should be declared as it is not in line with the requirement in national legislation. Under Malaysia Food Regulations 1985, the functional class of food additive and INS number should be declared.

Recommendation 30: Declarative of nutritive value

Malaysia agrees with the proposed drafting text for [name of product] for young children in paragraph 9.3 (a), (b) and (c).

Recommendation 31: Date marking and storage instructions

Malaysia proposes to follow the development on the date marking requirement that is currently been discussed in CCFL.

Recommendation 32: Information for use

Malaysia has no objection to the proposed information for use.

Recommendation 33: Additional Labelling requirements

Malaysia supports the words “and to enable consumers to make clear distinction between them” in paragraph 9.6.2 but proposes to delete the words “in particular as to the text, images and colours used”. Therefore, the sentence should be read as follows:

- **[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.~~]**

Recommendation 34: Product definition for older infants

Malaysia has no objection to the proposed definition.

Recommendation 35: Product definition for younger children

Malaysia does not support the addition of the last sentence and proposes to delete the statement “when nutrient intakes may not be adequate to meet nutritional requirements”. Malaysia is of the opinion that the statement 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: Name of product for older infants

Malaysia agrees with the proposed name Follow-up Formula for Older Infants.

Recommendation 37: Name of product for young children

Malaysia would like to propose the name for product for young children as follows:

- *Formulated milk-based (or soy-based) product for young children*

Malaysia’s proposal for the changes are for the following reasons:

- the word “formulated” is preferred as it denotes a product that has been prepared with nutritional needs of the young children in mind;
- the word “soy” specifically instead of the general term “plant-based” may be misused and some plant-based products of poor nutritional quality may be used to formulate the product.
- the word “product” is preferred as the term “drink/beverage” has the connotation of general beverages of any nutritional quality

NORWAY

Recommendation 1: Protein – older infants

1) Minimum amount

We support a minimum protein level of 1.6 g/100 kcal and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/100 kcal.

2) Footnote 5

We support a minimum value of 2.25 g/100 kcal for follow-up formula based on soy protein isolate, which is in line with EFSA and the EU Regulation on Infant Formula and Follow-On Formula. We agree with including "or non-goats" in the second sentence to be consistent with the first sentence.

3) Footnote 6

We support that formula based on non-hydrolysed protein containing less than 1.8 g protein, should be clinically evaluated by a competent national and/or regional authority.

We support a requirement stating that *all* formula based on hydrolysed protein should be clinically evaluated. This is in line with EFSA 2014, which emphasised that the safety and suitability of formula containing protein hydrolysates, including their minimum protein content, has to be established by clinical studies.

~~[~~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 **[all]** 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.~~]~~

We agree to combine the two sentences relating to the clinical evaluation of formula based on non-hydrolysed milk and formula based on hydrolysed protein.

Recommendation 2: Docosahexanoic acid – older infants

1) Minimum amount

During the discussions, we have supported mandatory addition of DHA, in line with EFSA and the new EU Regulation on Infant Formula and Follow-On Formula. EFSA has recommended that DHA should be added to all infant and follow-up formulas, in the range of 20-50 mg/100 kcal. In order to provide an adequate amount of DHA, we support a minimum of 20 mg DHA/100 kcal.

Recommendation 3: Fat – young children

We support to establish a minimum level for fat of 3.5 g/100 kcal, in order to accommodate formulations based on reduced fat (semi-skimmed) cows' milk.

Recommendation 4: Available carbohydrates – young children

We can agree to a maximum level for available carbohydrates of 12.5 g/100 kcal.

Recommendation 4 and 5: Available carbohydrates – young children

We are of the opinion that addition of sugars other than lactose in products for young children should be limited to 10% of available carbohydrates, in order not to increase the preference for sweet tastes, and meeting the WHO-recommendation.

We agree to set limit for sugars for mono- and disaccharides, and to include the wording of WHO that "mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate".

We strongly support that in addition to limiting the addition of sugars other than lactose, other carbohydrates contributing to sweet taste should be limited. We support the inclusion of a reference that "other sweet-tasting carbohydrates should not be added".

Recommendation 7: Calcium-to-phosphorous ratio – young children

We agree to not include any calcium-to-phosphorous ratio for [name of product] for young children.

Recommendation 8: Vitamin D – young children

1) Minimum amount

We principally support a minimum vitamin D level of 1.0 µg/100 kcal, which would align the minimum level with the value agreed for FUF for older infants, and such would be in line with the agreed approach.

We could however accept to deviate from the approach to align levels, to set a minimum level of 1.5 µg/100 kcal.

2) Maximum amount

We support a maximum vitamin D level of 3.0 µg/100 kcal, which would align the maximum level with the value agreed for FUF for older infants, as this would be in line with the agreed approach.

A caloric intake of 500 kcal with a minimum level of 3 µg/100 kcal would result in an intake of 15 µg/100 kcal, accounting for 100% of DIRV of 15 µg (EFSA 2016), thus meeting vitamin D requirements alone. A value of 3 µg/100 kcal would not lead to excessive intakes.

Recommendation 9: Preamble

We agree to the approach proposed by the Codex Secretariat and WHO, that being to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA resolutions.

Please find our selected wording in the Preamble statement 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).

Recommendation 10: Scope 1.1 – older infants

We can agree with the recommendation, since the proposed Preamble includes the statement that the standard does not apply to products covered by the Codex Standard for Infant Formula.

Recommendation 11: Scope 1.2 – older infants

We agree with the recommendation to include “labelling and analytical requirements”.

Recommendation 12: Scope 1.3 – older infants

We can agree to the recommendation, and support to use the word “shall”:

“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: Scope 1.4 – older infants

We agree to include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, as recommended by the Codex Secretariat and WHO. Consequently, provision 1.4 for follow-up formula for older infants can be deleted from the Scope section.

Recommendation 14: Labelling introductory paragraph – older infants

We agree to the recommended introductory paragraph, which include a reference to the applicability of the Codex General Standard for the Labelling of Pre-packaged Foods, the Guidelines on Nutrition Labelling and the Guidelines for Use of Nutrition and Health Claims. We also agree with emphasising the prohibition on the

use of nutrition and health claims for foods for infants and young children, unless specifically provided for in relevant Codex Standards or national legislation.

Recommendation 16: Name of the product – older infants

As 9.1.4 provides more guidance, we can agree to option 1.

Recommendation 17: List of ingredients – older infants

We support the recommended text.

Recommendation 18: Declaration of nutritive value – older infants

We agree with the recommendation.

Recommendation 19: Date marking and storage instruction – older infants

We agree with the recommendation.

Recommendation 20: Information for use – older infants

We support the recommended text. In addition, we support including a text in 9.5.5 similar to the provision in the EEA legislation (Article 6(3)(a) of delegated Regulation (EU) 2016/127), that the label of follow-up formula for older infants shall include the following information: "The decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs".

Recommendation 21: Additional labelling requirements – older infants

We agree with the recommended text. We support to include the text in square brackets in 9.6.4; "and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used".

Recommendation 34: Definition of follow-up formula – older infants

We support the recommendation.

Recommendation 34: Definition of follow-up formula – young children

We support the definition: "[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"

[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 do not agree with including the sentence "when nutrient intakes may not be adequate to meet the nutritional requirements" in the definition. This 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. However, the Committee has already agreed the product is not considered nutritionally necessary.

PHILIPPINES

General

The Philippines supports the review of the Codex Standards for Follow Up Formula and agrees with Recommendations 1-37 with revisions since these are consistent with previous Philippine Positions as justified by generally accepted scientific evidence.

Rationale

Specific

Recommendation 1

The Philippines is of the opinion that the minimum value of **1.6g/100kcal**could be considered as the minimum nutritional requirements for protein for older infants as defined by expert authorities. Expert authorities have lowered the protein requirements for infants and young children over the last decade (WHO/FAO/UNU, 2007; EFSA, 2013; Koletzko et al, 2013).

Similarly an expert group coordinated by the Early Nutrition Academy (ENA) provided guidance for protein levels of follow-up formula for older infants and recommended protein levels be lowered to 1.65 g/100 kcal based on metabolic requirements (Koletzko, 2013).

We recommend to retain the bracketed texts “2.25 g/100 kcal (0.54 g/100 kJ” in Footnote # 5. We also support deletion of brackets in these footnote statements: For follow up formula based on soy protein isolate a minimum value of 2.25g/100kcal (0.54g/100kJ applies. Follow up formula based on non-hydrolized milk protein containing less than 1.8 g protein/100 kcal (0.43 g/100 kJ) and follow up formula based on hydrolysed milk p/100 kcal protein containing less than 2.25 g protein /100 kcal (0.54 g/100 kJ) should be clinically evaluated **and assessed**by a competent national and/or regional authority.

Recommendation 2

The Philippines is in agreement with Guidance Upper Level for Docosahexanoic acid of 30 mg/100 kcal and a minimum level of 13 mg/100 kcal (3.1 mg/100 kcal). The minimum and GUL values are equivalent to average levels of DHA in breastmilk ((EFSA 2014; Brenna, 2007). The GUL of 30 mg/100 kcal is the maximum set in Infant Formula Codex standard in which DHA is an optional ingredient only.

We prefer the widest range approach since competent authorities may deviate from the minimum and maximum levels as appropriate based on the nutritional needs of the local population.

Recommendation 3

We supportthe proposed minimum level of 3.5 g/100 kcal for fat. This is closely similar to the levels found in breastmilk and concurs with the requirements for older infants by 2014 EPZA and 2015 IEG.

Recommendation 4

The Philippines support a maximum limit of 12.5 g/100 kcal (3.0 mg per 100 kJ) for total carbohydrates to ensure nutritionally appropriate contributions from follow-up formula for young children. This is consistent with the recommendation of Suthutvoravut et al (2015) that available carbohydrates should contribute 9-14 g/100 kcal with >50% from lactose.

Recommendation 5

We reiterate support for a maximum 12.5 g/100 (3.0 mg per 100 kJ) kcal for available carbohydrate. However, sugar content (mono and di-saccharides), other than lactose should not exceed **10% of total energy** based on WHO Recommendation. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 10% of available carbohydrates or 5% of total energy content. These statements are consistent with other Codex Standard for Infant Formula and Codex Standard for Cereal Based Foods for Older Infants and Young Children.Restriction on sugar is also based on 2015 WHO recommendation that both adults and children reduce the intake of free sugars to less than 10% of energy and conditionally recommended a further reduction to less than 5% of energy.

We support the retention of the bracketed text **[**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**.]**

Recommendation 6

We will not object to the conversion of the percentage limit for sugar based on the energy density for (name of product) for young children.

We support 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

We support that there is no need to establish a calcium-to-phosphorous ratio as it does not fulfil any of the principles for mandatory addition. We also agree with the following arguments: a) the follow-up formula is a part of an increasingly diversified diet providing enough phosphorous from other sources (phosphorous is not a key nutrient in cow’s milk); and b) WHO/FAO have not established a dietary intake reference value for phosphorous and there is no evidence for phosphorous intake being inadequate.

Recommendation 8

A mandatory addition of vitamin D to product for young children at a minimum of 1.5µg/100kcal as proposed by ENA is supported by the Philippines. Vitamin D insufficiency in young children still exists even in some lower latitude countries. A maximum of 4.5mcg/100kcal, which corresponds to 3 times the minimum level, seems to be appropriate GUL level. We believe an upper limit for vitamin D is needed due to the potential toxicity of Vitamin D.

Recommendation 9

We are in agreement of the need to include scientific reference to relevant WHO documents and WHA resolutions to the Preamble in the Standard for Follow up Formula. Thus, we support the following statements:

We support deletion of the brackets in this paragraph. 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, ~~[~~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.

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 of Infant and Young Child Feeding. Relevant WHO Guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been ~~[~~endorsed <u>/~~supported~~</u>~~]~~ by member states ~~[may also]~~provide guidance to countries in this context. We believe that statements on the reference to WHO documents and WHA resolutions should be definite considering their relevance. Hence, we recommend deletion of bracketed texts “as appropriate” and “may also”.

Recommendation 10

We support the statement “1.1 This section of the Standard applied to Follow-Up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

Recommendation 11

We support retention of the bracketed text in the statement “This section of the Standard contains compositional, quality, safety, labeling and analytical requirements for Follow-Up Formula for Older Infants.”

As we understand it, analytical requirements would mean methods of analysis – which is always part of a standard.

Recommendation 12

The Philippines supports deletion of the brackets in the statement on Section 1.3: Only products that comply with the criteria laid down in the provisions of this section of this Standard <u>shall</u> be presented as Follow-up Formula for Older Infants. The use of shall connotes mandatory requirements.

Recommendation 13

The Philippines is in agreement with inclusion of reference to WHO documents and WHA resolutions within the Preamble rather than the Scope and that this reference be consistent with the recommendation of the Codex Secretariat and WHO as presented within Section 5.3. However, in the event that the Standard for [Name of Product] for Young Children is presented on a separate Standard, the subsequent Preamble should make reference to WHO documents and WHA resolutions in that particular standard.

Recommendation 14

The Philippines supports the labeling requirements of follow up formula to be in compliance with the Codex General Standard for the Labeling of Pre-packaged Foods, the Guidelines on Nutrition Labeling and the Guidelines for Use of Nutrition and Health Claims. We strongly support the prohibition on the use of health and nutrition claims for foods for infants and young children as provided in the Codex Guidelines for Health and Nutrition Claims.

Recommendation 15

We fully support Recommendation 15 on the prohibition of the use of health and nutrition claim for the Standard for Follow Up Formula consistent with the Guidelines on Health and Nutrition Claims and in compliance with the International Code of Marketing Breast-milk Substitutes; the Philippine local regulations (Executive Order 51 or the Milk Code) and WHO Guidance on Ending Inappropriate Marketing of Food for

Infants and Young Children. If allowed, promotion of nutrition and health claims on this product for young children may potentially undermine breastmilk and breastfeeding practices. Therefore, any nutrition and health claims should not be allowed on the labels of follow up formula for older infants.

Recommendation 16

We support deletion of the brackets in the statement "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.

We support Option 2 with revision and recommend that these statements be under 9.1.3:

9.1.3(a) If ~~name of~~ animal milk is the only source of protein, the product may be labelled ~~'Follow Up Formula Older Infants~~ Based on [name of animal]milk [protein].

9.1.3(b) If ~~name of~~ plant milk is the only source of protein, the product may be labelled ~~'Follow Up Formula Older Infants~~ Based on [name of plant][protein].

9.1.4 A product which contains neither milk nor any milk derivative **s**hallbe labelled "contains no milk or milk products" or an equivalent phrase. In addition to 9.1.4, the use of "shall" is more reinforcing rather than the use of "may" which connotes "optional use".

Recommendation 17

We will not object to this statement deleting the bracketed text**:**

> **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.

We support retention of the bracketed text in this statement with revision:

> **9.2.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. **Food additives maybe optionally declared as INS number in addition to declaration of specific or common name.**

Recommendation 18

We are in agreement to delete the brackets and will not object to deletion of bracketed or:

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 gramsof 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.

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

Recommendation 19

The Philippines is of the opinion that there is a need to modify the proposed text on Date Marking and Storage Instructions as necessary and adopt any changes proposed at CCFL to be consistent with the text and outcomes of the discussions at the Codex Labeling Committee meeting in October 2017.

Recommendation 20

We support the following statements with deletion of the brackets in the first sentence of 9.5.1 and bracketed texts and revision of Section 9.5.1 for brevity:

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 product], 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 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 Thelabeloffollow-upformulaforolderinfantsshallincludeastatementthattheproductshallnotbeintroducedbefore6months ofage,**isnottobeusedasasolesourceofnutritionas olderinfantsshouldreceivecomplementaryfoodsinadditiontotheproduct.**

Recommendation 21

We support Option 2 with the following revisions in letter d:

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) **It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue up to two years of age or beyond.**

It is critical to include statement under letter d to comply with the International Code of Marketing Breastmilk Substitute.

9.6.2. We support Option 2 retaining the square brackets:

~~[~~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 use 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. We **do not support** addition of the phrase "~~unless this has been specifically approved by relevant nation regional or international regulatory authority"~~ since it may open allowance for endorsement tantamount to undermining breastmilk or practiceof breastfeeding.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

We support inclusion of this statement as 9.6.4 and retention of the bracketed text "Products shall belabelled 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.~~]~~

Recommendation 22

We are in agreement with this statement for Section 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

We support retention of the bracketed text in the statement “This section of the Standard contains compositional, quality, safety, labeling and analytical requirements for Follow-Up Formula for Older Infants.”

As we understand it, analytical requirements would mean methods of analysis – which is always part of a standard.

Recommendation 24

We are of the opinion that this statement is clearer and should indicate that only products that complywith the provisions of this Standard shall be named as (Name of product) for Young Children: “Onlyproducts that comply with the criteria laid down in the provisions of this section of this Standard **shall** bepresented as (Name of product) for Young Children.

Recommendation 25

The Philippines is in agreement with inclusion of reference to WHO documents and WHA resolutions within the Preamble rather than the Scope and that this reference should be consistent with the recommendation of the Codex Secretariat and WHO as presented within Section 5.3. However, in the event that the Standard for [Name of Product] for Young Children is presented on a separate Standard, the subsequent Preamble should make reference to WHO documents and WHA resolutions.

We recommend inclusion of the WHA 69.9 (**Ending the Inappropriate Promotion of Foods for Infants and Young Children).** We areof the opinion that its inclusion is critical since label is considered part of promotional or advertisingmaterial.

Recommendation 26

The Philippines supports the labeling requirements of follow up formula to be in compliance with the Codex General Standard for the Labeling of Pre-packaged Foods, the Guidelines on Nutrition Labeling and the Guidelines for Use of Nutrition and Health Claims. We strongly support the prohibition on the use of health and nutrition claims for foods young children as provided in the Guidelines for Health and Nutrition Claims.

Recommendation 27

We fully support Recommendation 26 on the prohibition of the use of health and nutrition claim for the Standard for [Name of Product] consistent with the Codex Guidelines on Health and Nutrition Claims and in compliance with the International Code of Marketing Breast-milk Substitutes; the Philippine local regulations (Executive Order 51 or the Milk Code) and WHO Guidance on Ending Inappropriate Marketing of Food for Infants and Young Children. If allowed, promotion of nutrition and health claims on this product for young children may potentially undermine breastmilk and breastfeeding practices. Therefore, any nutrition and health claims should not be allowed on the labels of [name of product] for young children.

Recommendation 28

We support deletion of the brackets in the statement “The name of the product shall be Follow-up Formula 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.

We support Option 2 with revision and recommend that these statements be under 9.1.3:

9.1.3(a) If ~~name of~~ animal milk is the only source of protein, the product may be labelled ~~‘Follow Up Formula Young Children~~ Based on ~~[~~name of animal~~]~~milk ~~[~~protein~~]~~.

9.1.3(b) If ~~name of~~ plant milk is the only source of protein, the product may be labelled ~~‘Follow Up Formula Young Children~~ Based on ~~[~~name of plant~~][~~protein~~]~~.

9.1.4 A product which contains neither milk nor any milk derivative **s**hallbe labelled "contains no milk or milk products" or an equivalent phrase. In addition to 9.1.4, the use of “shall” is more reinforcing rather than the use of “may” which connotes “optional use”.

Recommendation 29

We will not object to this statement deleting the bracketed text**:**

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.

We support retention of the bracketed text in this statement with revision:

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **Food additives may be optionally declared as INS number in addition to declaration of specific or common name.**

Recommendation 30

We are in agreement to delete the brackets and will not object to deletion of bracketed or:

9.3 Declaration of Nutritive Value

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

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

d) 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.

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

Recommendation 31

The Philippines is of the opinion that there is a need to modify the proposed text on Date Marking and Storage Instructions as necessary and adopt any changes proposed at CCFL to be consistent with the text and outcomes of the discussions at the Codex Labeling Committee meeting in October 2017.

Recommendation 32

We support the following statements with retention of brackets in 9.5.1 and deletion of the bracketed texts in the 2nd statement in 9.5.1 for brevity:

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 product~~], 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 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~~] diet.

Recommendation 33

9.6 Additional Labelling Requirements

The Philippines does not support 9.6.1 but instead propose the following statements:

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) **It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue up to two years of age or beyond.**

We support retention of the bracketed statement in 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]**."

Recommendation 34

We wish to reiterate this definition for product for follow-up formula for older infant:

- ***Follow-up Formula for Older Infants*** *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.*

Follow-up formula for older infants can still be considered as breast-milk substitute to help meet the nutritional requirements of older infants. It serves as a transition from the introduction of complementary foods to eventual consumption of family meals. Labelling for this product should also indicate that Follow-Up Formula for Older Infants is only a substitute in cases where breastfeeding is impossible.

Recommendation 35

We maintain that the product for young children could still be considered as a breastmilk substitute and is covered by the International Code of Marketing BreastmilkSubstitute, hence we proposed that this be considered in the definition. We support retention of the bracketed texts with revision.

[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 and**for use as a substitute for breast-milk** [in order to contribute to the nutritional needs of young children] ~~[when nutrient intakes may not be adequate to meet nutritional requirements].~~

Recommendation 36

The Philippines is supportive of this statement:

That CCNFSDU agree to adopt the name ***Follow-up Formula for Older Infants*** as the name of product for the 6 – 12 month age group (older infants).

Recommendation 37

We support "Formulated Milk-Based (or Plant-Based) Drink for Young Children". There may be no need to indicate the source of protein since it is part of mandatory declaration on the label. The product name would be too long if the source of protein is part of the product name.

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TANZANIA

Background of review of the standard

At the 38th Session, an electronic working group chaired by New Zealand, co-chaired by Indonesia and France was established to work in English only with the following terms of reference:

a. Finalise the minimum protein requirements and levels for the optional addition of DHA on the Essential Composition of Follow-up Formula for older infants (6-12 months) (Sub-section 3 of Section A);

b. Finalise the outstanding requirements for the Essential Composition of product for young children (12 - 36 months) (Sub-section 3 of Section B);

c. Finalise the product definitions contained within Definition 2.1 including the name of product for 12-36 months;

d. Review the Scope and Labelling Sections with a point of differentiation at 12 months, for Section A and Section B of the draft Standard based on the discussions at CCNFSDU38, and propose draft text.

The electronic working group discussed the follow–up formula standard and developed 37 recommendations to be considered by the 39th Session of CCNFSDU. The 37 recommendations were discussed and comments and rationale provided as indicated below:

Issue: Recommendation 1: That CCNFSDU agree to revise the protein requirements as follows: that a minimum protein level of 1.6 g/100 kcal is established and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/ 100 kcal.

Comment: Tanzania do not support the recommendation of a minimum of 1.6 g/100Kcal. We support the adoption of 1.8 g/Kcal. This is because the EFSA opinion, which the 38th session of CCNFSDU agreed to wait its publication, indicated that 1.6 g/100 Kcal is applicable to countries with good alternatives sources of protein and that the guidance was specifically applicable to European countries. In developing countries especially in Africa, alternative protein sources such as grains and legumes are generally regarded as poor sources of proteins. It is based on this that we recommend the minimum level of 1.8 g/100Kcal. A footnote may be introduced to indicate that countries with good sources of alternative protein may consider a minimum of 1.6 g/Kcal.

Issue: Recommendation 2: That CCNFSDU agree:

That the minimum in the footnote for the optional addition of docosahexaenoic acid is set to 13 mg/100kcal (3.1 mg/100 kJ).

That the agreed GUL (Guided Upper Limit) of 0.5% of total fatty acids is converted to 30 mg/100 kcal (7.9 mg/100 kJ).

Comment: Tanzania support the recommendation as proposed because the major functional role of DHA is in cognitive and vision during child development. It therefore follows that DHA is a critical nutrient that must be provided in early child growth. It is generally known that children who are optimally breast fed usually have a better cognitive development compared to those who are not breast fed and this is generally attributed to the DHA. However, despite this critical role of DHA, studies of human milk have shown varying levels depending on the food consumed with those consuming sea food having higher levels. A minimum of 13 mg/100 Kcal to 20 mg/100 Kcal are likely to have positive impact on brain development and vision. Therefore we support the current level which is an acceptable compromise for the minimum level of DHA.

Issue: Recommendation 3: That CCNFSDU agree to establish a minimum level for fat of 3.5 g /100 kcal (0.84 g/100 kJ).

Comment: Tanzania do not support the recommendation to adopt 3.5 g/100 Kcal. We propose a minimum of 4 g/100 Kcal because a minimum of 3.5 g/100Kcal will translate to fat contributing 24.5 % of the energy in the product. This is low for the targeted population which should ideally get about 30 - 35 % of the energy in their diet from fat due to their increased activity. A minimum of 4 g/100 Kcal will contribute 28 % energy from fat which is close to 30 % and therefore a good compromise.

Issue: Recommendation 4: That CCNFSDU agree to establish a maximum level for available carbohydrates of 12.5 g/100 kcal (3.0 g/100kJ).

Comment: Tanzania support the recommendation because the proposed minimum (12.5 g/100Kcal) will contribute 50 % of the energy of the product contributed by carbohydrates which is consistent with dietary recommendation of 50 – 60 % of energy coming from carbohydrates.

Issue: Recommendation 5: That CCNFSDU:

1. Agree to establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates.

2. Agree that sweet tasting carbohydrates are restricted in accordance with the amended footnote 4 below.

3. Considers the need to limit the addition of non-carbohydrate ingredients with the purpose of imparting a sweet taste.

Comment: Tanzania support the recommendation because mono and di-saccharides contribute to dental caries and contribute in increasing glycemic index. They also influence the child feeding pattern due to sweetness they impact on the food which may lead to the infant or children rejecting other nutritious foods that may not necessary have the sweet taste impacted by the mono and di-saccharides.

Issue: Recommendation 6: 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.

Comment: Tanzania support the recommendation because it is an easy way of reporting results of analysis as well as for formulation purposes.

Issue: Recommendation 7: That CCNFSDU agree that no calcium-to-phosphorous ratio is included for [name of product] for young children.

Comment: Tanzania support the recommendation because it is generally known that cow's milk is not a good source of phosphorus. Therefore since the follow-up formula is based on cow's milk, it will be technologically difficult to achieve any of the proposed ratios. In addition, follow-up products are part of complementary feeding which will be expected to provide more phosphorous.

Issue: Recommendation 8: That CCNFSDU agree to the mandatory addition of vitamin D and minimum and maximum levels

Comment: Tanzania do not support because the addition of vitamin D should be optional nutrient especially for countries with a good exposure to sunlight as they will be able to synthesize vitamin D. A footnote may be considered for countries with limited sun exposure to have vitamin D as mandatory nutrient.

Issue: Recommendation 9: That

1) CCNFSDU agree to the approach proposed by the Codex Secretariat and WHO, 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.

That CCNFSDU agree to the following Preamble statement proposed by the Codex Secretariat and WHO, and select the preferred wording from that presented in square brackets:

Comment: Tanzania support the introduction of a preamble with the following amendment to the text. The proposed changes to the text as indicated by the strike through and bold with proposed inclusion highlighted only

*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 **WHA resolutions 39.28, 63.23, 69.6 and any** 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).

Rationale: The preamble should clearly promote and protect breast feeding practices without any ambiguity and that specific known WHA resolution to which our countries have ratified during the World Health Assembly should be explicitly mentioned in absolute terms and provide the provision for any other WHA resolution related to these products that may be adopted in future to be applicable without the need of revisiting the standard.

Issue: Recommendation 10: That CCNFSDU agree to the following statement for Section 1.1:

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.

Comment: Tanzania support the proposed text because the statement introduces the section covering older infants.

Issue: Recommendation 11: 1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.

Comment: Tanzania support the proposed text because it provides for the requirements of labeling which is important in these products

Issue: Recommendation 12: That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

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.

Comment: Tanzania support the use of the term 'Shall' in the statement because the use of 'shall' makes it mandatory for the products to comply as opposed to 'should'. All products declared as follow up formula must comply with the standard.

Issue: Recommendation 13: That CCNFSDU agree to:

- *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.*

- *delete provision 1.4 for follow-up formula for older infants from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.*

Comment: Tanzania can support the recommendation provided that the text is amended as proposed in our comments in recommendation 9.

Rationale: The objective is including normative reference to the WHA resolution in absolute terms in the standard, whether in scope or preamble for the purposes of promoting and protecting breast feeding practices.

Issue: Recommendation 14: That CCNFSDU agree to the following introductory paragraph to the Labelling Section for follow-up formula for older infants (Section A):

Comment: Tanzania propose the following amendment to the proposed text

*The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) shall apply in follow-up formula for older infants. **Nutrition and health claims are prohibited in foods for infants and young children**. Where nutrition and health claim **may be** provided in a relevant Codex Standards or national/regional legislation, the claims shall be done in accordance to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).*

Rationale: To give prominence to the provision within the International code of marketing of breast milk substitutes that prohibits nutrition and health claims in infant and young children foods. In addition all the existing 5 Codex standards for products for infants and young children have prohibited nutrition and health claims including the standard for follow-up formula. Therefore emphasis to prohibition should be prioritized before giving the unlikely option of having the claims based on national/regional legislations.

Issue: Recommendation 15: A decision on the need to revisit nutrition claims on the completion of NRVs for infants and young children is not required by CCNFSDU at this point in time.

Comment: Establishment of NRV should not hold the review of this standard because the discussions on development of NRV for young children has not started and thus holding this review will lead to unnecessary delay in the revision of the standard.

Issue: Recommendation 16: OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

Comment: Tanzania support option 2 on deletion of 9.1.4 because since 9.1.3 which require declaration of protein sources covers well the issues related to source of protein in the products as elaborated under the proposed clause 9.1.4.

Issue: Recommendation 17: 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. **[The INS number of Food additives may also optionally be declared. ~~the~~ ~~INS number].~~**

Comment: Tanzania support the recommendation with slight editorial amendment on the last sentence of 9.2.2 as highlighted. This is because the ingredients used whether optional or otherwise must be declared and thus there will be no need to emphasize on the optional ingredients. The editorial amendment was to improve the flow of the sentence.

Issue: Recommendation 18: 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.

Comment: Tanzania support the proposed text as it provides for declaring the nutrients in absolute values which will be easy to the consumers as opposed to having the nutrients declared per Kcal (KJ) which most consumers do not understand.

Issue: Recommendation 19: As this paper was written prior to CCFL44, it is recommended that CCNFSDU agree to modify the above text (as necessary) and adopt any changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017.

Comment: Tanzania support the proposed text because it is a recommendation from the competent committee on labeling, CCFL.

Issue: Recommendation 20: That CCNFSDU agree to the following text for Section 9.5 and consider the proposed rewording of provision 9.5.1

Comment: Tanzania support and agree with the proposed text because it will ensure good hygienic practices during preparation of the product and thus protect the consumers.

Issue: Recommendation 21: [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.**]

Comment: Tanzania support the recommendation as revised and in particular open the square brackets as proposed for inclusion under clause 9.2.4. This is because studies have shown that due to similarity of packages, most consumers are confused and end up using the wrong formula for different age bracket. The proposed text will ensure clear difference in packaging and labeling different formulas thus making it easy for consumers to use the right formula at the specific age.

Issue: Recommendation 22: That CCNFSDU agree to the following statement for Section 1.1:

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.

Comment: Acceptable as drafted

Rationale: The statement is an opening phrase to the section.

Issue: Recommendation 23: That CCNFSDU agree to the following statement for 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.

Comment: Acceptable

Rationale: The statement is an opening phrase to the section.

Issue: Recommendation 24: That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

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.

Comment: Tanzania support the use of the word 'Shall' as opposed to Should

Rationale: This will make it mandatory for the product to comply with the standard

Issue: Recommendation 25: That CCNFSDU agree:

- to 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 delete provision 1.4 for [name of product] for young children from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.

Comment: Same comment as recommendation 9

Rationale: Same rationale as recommendation 9

Issue: Recommendation 26: That CCNFSDU agree to the following introductory paragraph to the Labelling Section for [name of product] for young children (Section B):

Comment: We propose the following amendment to the proposed text

The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) shall apply in follow-up formula for older infants. ***Nutrition and health claims are prohibited in foods for infants and young children****. Where nutrition and health claim is provided in a relevant Codex Standards or national legislation, the claims shall be done in accordance to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).*

Rationale: To give prominence to the provision within the International code of marketing of breast milk substitutes that prohibits nutrition and health claims in infant and young children foods. In addition all the existing 5 Codex standards for products for infants and young children have prohibited nutrition and health claims including the standard for follow-up formula. Therefore emphasis to prohibition should be prioritized before giving the unlikely option of having the claims based on national/regional legislations.

Issue: Recommendation 27: A decision on the need to revisit nutrition claims on the completion of NRVs for infants and young children is not required by CCNFSDU at this point in time.

Comment: The NRV should not hold the review of this standard

Rationale: The NRV for young children has not started and thus holding this review will lead to unnecessary delay in the revision of the standard.

Issue: Recommendation 28: OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

Comment: Tanzania support option 2 on deletion of 9.1.4

Rationale: We support deletion of 9.1.4 since 9.1.3 covers well the declaration of the source of protein

Issue: Recommendation 29: 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.

[The INS number of Food additives may also optionally be declared. ~~the INS number~~].

Comment: We support the recommendation with slight editorial amendment on the last sentence of 9.2.2

Rationale: The ingredients used whether optional or otherwise must be declared and thus there will be no need to emphasize on the optional ingredients. The editorial amendment was to improve the flow of the sentence.

Issue: Recommendation 30: 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.

Comment: Tanzania support the proposed text

Rationale: It provides for declaring the nutrients in absolute values which will be easy to the consumers as opposed to having the nutrients declared per Kcal (KJ) which most consumers do not understand.

Issue: Recommendation 31: As this paper was written prior to CCFL44, it is recommended that CCNFSDU agree to modify the above text (as necessary) and adopt any changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017.

Comment: Tanzania support the proposed text

Rationale: It is a recommendation from the competent committee on labeling, CCFL.

Issue Recommendation 32: That CCNFSDU agree to the following text for Section 9.5 and consider the proposed rewording of provision 9.5.1

Comment: Tanzania support and agree with the proposed text

Rationale: The proposed text will ensure good hygienic practices during preparation of the product and thus protect the consumers.

Issue: Recommendation 33: [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.]**

Comment: Tanzania support the recommendation as revised and in particular the proposed inclusion under clause 9.2.4 (in square brackets)

Rationale: Studies have shown due to similarity of packages, most consumers are confused and end up using the wrong formula for different age bracket. The proposed text will ensure clear difference in packaging and labeling different formulas thus making it easy for consumers to use the right formula at the specific age.

Issue: Recommendation 34: That CCNFSDU agree to the following definition for follow-up formula for older infants: *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*.

Comment: Tanzania support the definition

Rationale: The definition clearly describes the product as produced.

Issue: Recommendation 35: That CCNFSDU consider the following proposal for the definition of (name of product) for young children, including the text in square brackets.

[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].

Comment: Tanzania do not support the proposed text but amend it to read as,

[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].**~~

Rationale: WHO had declared that follow-up formula are not nutritionally important and thus the proposed definition is trying to introduce a role of follow-up formulas in nutritional status of the young children. This definition will be consistent with the definition of follow-up formula for older infants

Issue: Recommendation 36: That CCNFSDU agree to adopt the name Follow-up Formula for Older Infants as the name of product for the 6 – 12 month age group (older infants).

Comment: Tanzania propose the name to be **Formula for older infants**

Rationale: The words, 'follow-up' is not necessary in the name of the product and it also gives an impression that the product is used after a previous product has been in use. However, it should be noted that there is no difference in composition of this product and infant formula. In addition the difference in formula described under Codex standards is mainly on the age which the product may be used.

Issue: Recommendation 37: That CCNFSDU agree to either of the following two names for product for young children.

- Formulated drink for young children
- Young child formulated drink

Comment: Tanzania propose the name to be **formula for young children**

Rationale: To be consistent and separate the products based on age i.e. infant formula, formula for older infant and now formula for young children.

THAILAND

General Comments

We would like to propose that the document should be separated to the Standard for Follow-up Formula for Older Infants and the Standard for Follow-up Formula for Young Children or Other Name in order to be clear and easy for the use of document in practice.

Specific Comments

Our comments for specific sections of the document (CX/NFSDU 17/39/4) are as follows:

- **Appendix II**

Proposed Draft Revised Standard for Follow-Up Formula (CODEX STAN 156-1987)

[PREAMBLE]

- We agree with the proposed text with our recommendation to insert the word "promote" in the first sentence as follows:

"The Codex Alimentarius Commission acknowledges the need to ~~[~~**protect*, promote* and support ~~/ recognize]~~ 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 ~~[~~**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).”

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

Section 1 [SCOPE]

- We agree with the proposed text with the inclusion of “labelling” in 1.2, meanwhile “and analytical” should be still placed in a square bracket. For 1.3, “shall” should be used in the provision, rather than “should”. So, the scope should read:

“[SCOPE]

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.

1.2 This section of the Standard contains compositional, quality, safety, ~~[~~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.”

Section 2: DESCRIPTION

2.1 Product Definition

2.1.1

- We agree with proposed text in section 2.1.1:Follow-up formula for older infants that should read:

“**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.~~**]**~~”

Section 3: ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

- From our view, for protein, the minimum level should be 1.8 g/100 kcal and the maximum level should be 0.43 g/100 kJ**,** rather than the levels proposed by the EWG.

Footnote 5

- To be consistent with the first sentence, the word “or non-goat” should be included in the footnote.

Footnote 6

- It is proposed that the current wording of footnote 6 in the standard should be retained as it is, meanwhile the additional text proposed by the EWG should not be included.

The mentioned sections should then read:

“a) Protein 2), 3), 4)

Unit	Minimum	Maximum	GUL
g/100 kcal	~~**[**~~1.8~~**]** **[1.6]**~~ 5),6)	3.0	-
g/100 kJ	~~**[**~~0.43~~**]** **[0.38]**~~ 5),6)	0.72	-

“5) The minimum value applies to cows’ and goats’ milk protein. For follow-up formula based on noncows’ ~~**[**~~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 (0.54 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 protein/100 kJ)] and follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal (0.54 g rotein/100 kJ)] should be clinically evaluated by a competent national and/or regional authority.]**~~”

3.2 Optional Ingredients

Docosahexaenoic acid

- We agree with the proposed GUL of Docosahexaenoic acid of 30 mg/100 kcal with the inclusion of "13 mg/100 kcal (3.1 mg/100 kJ)" in footnote 21. The section should then read:

"Docosahexaenoic acid [21)]

Unit	Minimum	Maximum	GUL
			~~[to be fixed after the fat content has agreed upon~~
mg/100 kcal	-	-	~~[~~30~~]~~
mg/100 kJ	-	-	~~[~~7.9~~]~~

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, a minimum level of ~~[20 mg/100 kcal]~~ ~~[~~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 concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs."

Section 9. [LABELLING]

9.1 The Name of the Product

9.1.2

- We agree with the proposed text with the inclusion of "or regional" in the provision.

9.1.4

- We agree with Option 1 to split provision 9.1.4 into two.

9.1.5

- To be clear, the word "shall" should be used in this provision, regarding labelling for a product which contains neither milk nor any milk derivative.

Therefore, Section 9.1 The Name of the Product should read:

"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 'Followup 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~~] [may]~~ be labeled "contains no milk or milk products" or an equivalent phrase."

9.2 List of Ingredients

9.2.1

- We agree with the proposed text with the removal of "including optional ingredients" from the provision.

9.2.2

- We agree with the proposed text with the inclusion of "Food additives may also optionally declare the INS number" in the provision.

Section 9.2 List of Ingredients should then read:

"**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~~]~~."

9.3 Declaration of Nutritive Value

- Sub-section d, e, f should be revised to a, b and c respectively.

- The word "as well as" should be used in the revised a and b.

Section 9.3 Declaration of Nutritive Value should then read:

"**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) ~~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.

b) ~~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.

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

9.4 Date Marking and Storage Instructions

- For 9.4.1, it is proposed that the term "Expiry Date" should be used in this provision, rather than "Best Quality Before Date" proposed by the EWG. And, we agree with the proposed text that should read:

"9.4 Date Marking and Storage Instructions

9.4.1 The **"Best Before Date" or "*Expiry Date*** ~~**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).~~]~~

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 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 there on.

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

9.5 Information for Use

- We agree with the proposed text with the inclusion of 9.5.6 in this section. And, the section should read as follows:

"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.~~]~~**"**

9.6 Additional Labelling Requirements

- We agree with the proposed text of 9.6.1 with the inclusion of sub-section a, and the removal of the word "an independent**"** in c. And, 9.6.2 and 9.6.4 should be included in this section as proposed by EWG. So, this section should read:

"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**~~ ***a*** 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 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.**~~]~~**"**

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

Section 1 [SCOPE]

- We agree with the proposed text with the inclusion of "labelling" in 1.2, meanwhile "and analytical" should be still placed in a square bracket. For 1.3, "shall" should be used in the provision, rather than "should". So, the scope should read:

"[SCOPE]

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.

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

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."

Section 2 DESCRIPTION

2.1 Product Definition

- For 2.1.1, we agree with the proposed text with the inclusion of the text "a progressively diversified" and the removal of all square brackets**.** The provision should then read:

"**2.1.1 [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**~~]~~."

Section 3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

b) Lipid

- The minimum level for lipid should be 3.5 g/100 kcal and 0.84 g/100 kJ as follows:

"b) Lipids**)

Total fat

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	~~[~~3.5~~]~~ ~~or [4.0] or [4.4]~~	-	-
g/100 kJ	~~[~~0.84~~]~~ ~~or [0.96] or [1.1]~~	-	-"

c) Carbohydrates

- The maximum level for carbohydrates should be 12.5 g/100 kcal.

Footnote 4

- From our view, carbohydrates used in the product should be lactose in milk. Sucrose and/or fructose should not be added in the product.

- And, we would like to propose that if carbohydrates other than lactose are added in the product, those carbohydrates' sweetness should be equal or less than lactose or their Dextrose Equivalent (DE) should be 5-20 such as oligosaccharide, glucose polymer and maltodextrin.

- The additional text proposed by the EWG should not be included in the footnote.

The section should then read as follows:

"c) Carbohydrates

Available cabohydrates[4)]

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	-	~~[12.0] or [~~12.5~~]~~	-
g/100 kJ	-	~~[2.9] or [~~3.0~~]~~	-

[4)] Lactose should be the preferred carbohydrates 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.~~ ***Sucrose and/or fructose should not be added in [name of product]. If carbohydrates, other than lactose are added in [name of product], those carbohydrates' sweetness should be equal or less than lactose or their Dextrose Equivalent (DE) should be 5-20 such as oligosaccharide, glucose polymer and maltodextrin.***

~~**[Mono- and disaccharides], other than lactose, should not exceed 20% of available carbohydrate. [Monoand 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.]"~~

Ratio calcium/phosphorous

- As proposed by the EWG, we agree with the removal of "Ratio calcium/phosphorous" from 3.1: Essential Compositions.

Vitamin D

- We agree with the proposal to include Vitamin D in Essential Compositions with the minimum level of 1.5 µg /100 kcal and maximum level of 4.5 µg /100 kcal as follows:

"~~[~~**Vitamin D**~~]~~

Unit	Minimum	Maximum	GUL
µg [9)] /100 kcal	~~[~~1.5~~]~~ ~~or [1.0]~~	~~[~~4.5~~]~~ ~~or [3.0]~~	-
µg [9)] /100 kJ	~~[~~0.36 ~~]~~ ~~or [0.24]~~	~~[~~1.08~~]~~ ~~or [0.72]~~	-

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

Section 9. [LABELLING]

9.1 The Name of the Product

- We agree with the proposed text with our preferences as follows:

9.1.2

- The word "or regional" should be included in the provision.

9.1.4

- We agree with OPTION 1 which splits 9.1.4 in two, including a and b with our preferences.

9.1.5

- The word "shall" should be used in this provision, rather than "may".

Section 9.1 should then read:

"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.~~]~~

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."

9.2 List of Ingredients

- We agree with the text proposed by EWG with the removal of "including optional ingredients" in 9.2.1 and the inclusion of "Food additives may also optionally declare the INS number" in 9.2.2. The section should then read:

"**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~~]~~."

9.3 Declaration of Nutritive Value

- Sub-section d, e, f should be revised to a, b and c respectively.

- The word "as well as" should be used in the revised a and b.

Section 9.3 Declaration of Nutritive Value should then read:

"**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) ~~**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.

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

9.4 Date Marking and Storage Instructions

- For 9.4.1, our proposal is to use the term "Expiry Date" in this provision, instead of "Best Quality Before Date" proposed by the EWG. And, we agree with the proposed text with our preferences as follows:

"9.4 Date Marking and Storage Instructions

9.4.1 The **"Best Before Date" or "*Expiry Date*** ~~**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).~~]~~

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 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."

9.5 Information for Use

- We agree with the proposed text as follows:

"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 ~~[~~**diversified**~]~~ ~~[balanced]~~ diet.~~]~~**"**

9.6 Additional Labelling Requirements

- We agree with the proposed text with the inclusion of 9.6.1 and 9.6.2 in the section as follows:

"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**~]~~."

EUROPEAN FOOD LAW ASSOCIATION (EFLA)

1. General question as to whether WHO documents and WHA resolutions must be referred to in the Standard (as it is in the Standard for Infant Formula).

EFLA notes that it has been acknowledged by the eWG members that this question may also impact other Committees and other Codex standards and guidelines. It is therefore a very important question which has not only political impact, but also legal consequences, and should, in EFLA view, be rather decided at the Commission level.

From a general legal point of view, EFLA has strong doubts as to including references by FAO and WHO policies and resolutions in a Codex Standard.

The parent organizations, FAO and WHO, are mandated to set policies, strategies and guidelines in the areas of food security and public health, respectively. The Codex mandate is however confined to set food standards that serve to protect consumer health and ensure fair practices in food trade.

It is not disputed that Codex Standards should not contradict the policies of WHO and FAO, and that Codex should allow the enforcement of these policies by the national governments. In that sense, EFLA agrees that when setting up standards, Codex members should be *informed* about the policies of WHO and FAO, and Codex must take them into consideration in order to prevent contradicting standards.

However, Codex should confine to it's specified mandate as per the procedural manual that describes the legal foundations of the functioning of the Codex Commission and its subsidiary bodies. This would allow the FAO/WHO members the decision to implement policies and resolutions and how to enforce them.

In this context, EFLA considers that Recommendation 9 submitted by the eWG regarding the Standard for Follow-up Formula (Agenda Item 4) is inappropriate and would constitute a risky precedent for future works of the Codex.

This strict distinction between the mandates of the parent organizations and Codex is all the more important as Codex standards have been recognized as a reference in international trade at the World Trade Organization (WTO) level. The agreement on Technical Barriers to Trade (TBT) refers in its article 2.4 to "*relevant international standards*" [7], among which Codex standards have been recognized in several dispute

[7] Art 2.4 of the TBT agreement : "*Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for*

resolution procedures after a thorough analysis of their relevance to the case at stake. As to the agreement on Sanitary and Phytosanitary measures (SPS), it explicitly mentions the Codex Alimentarius, among other standards, "*to promote (…) the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures*" (article 3.4). Inclusion of WHA resolutions, which are of political nature, in Codex standards would undermine the credibility and the relevance of these standards, which should remain purely scientifically internationally agreed references.

2. Question regarding labeling and communication

It has been suggested that the labeling of Follow-up Formula should be reviewed on the basis of what has been done for Infant Formula, to state that these products are not necessary in regard to breast milk feeding.

EFLA does not have any position on whether follow-up formula are or not breast milk substitutes, or whether they are or not "necessary". However, EFLA wishes to stress the following from a legal point of view.

2.1. Codex competence on labeling and publicity

According to the Codex Procedural Manual, the "Labeling" provision in a Codex Commodity standard should normally be limited to reference to the General Standard for prepackaged foods, in addition to indications such as the specific name, date marking and storage instructions. Other indications can be mentioned, but are limited to additions which are necessary for the interpretation of the General standard, provided that these can be justified fully.

When it comes to advertisement/ publicity, the CCFL, which will be competent for reviewing the labeling provisions of the Follow-up Formula Standard, has some competence, but it is limited, according to its terms of reference, "(*d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions*." (emphasis added).

On this basis, Codex is competent to prohibit or frame claims which would be misleading, eventually taking into account general health principles agreed on by the WHO (such as, for example, work on Nutrient Reference Values), but cannot go as far as imposing warnings.

The scope of Codex competence for labeling is therefore limited and cannot include, for example, general warnings against the use of a product. Such warnings can be decided by national governments, if they wish so, but have no place in a Codex Standard. A fortiori, considerations regarding marketing should also be excluded.

EFLA is pleased to see that this position is in line with the position taken by some delegations at the 44th session of the CCFL (16-20 October 2017) regarding possible future work on the labeling of alcoholic beverages: some delegations considered that health warnings on labels were outside the mandate of CCFL and that such issues should be dealt with by national governments (see Report, REP18/FL, point 55).

2.2. Non necessity of a product

The necessity of a product is not a question which is relevant in a product standard. There are many food products for which Codex Standards have been set up and whose "necessity" can be questioned.

Product standards are of technical nature, the purpose of which being to protect the consumer and to ensure fair practices in trade, whereas the necessity or not of a product for a consumer is something highly subjective which cannot be codified.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURER ASSOCIATIONS (ICGMA)

ICGMA appreciates the opportunity to comment on the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) circular letter CL 2017/75-NFSDU. ICGMA also wishes to acknowledge the significant amount of work by CCNFSDU to advance the Follow-up Formula (FUF) Standard (CODEX STAN 156-1987) to this point.

As the Committee continues to review the FUF standard, ICGMA offers one comment with regard to recommendation 9 in CX/NFSDU 17/39/4. ICGMA does not support adoption of language referencing World Health Organization (WHO) policies, guidances or recommendations that have not been endorsed by the World Health Assembly (WHA) and carefully reviewed by CCNFSDU for their consistency with Codex's high bar for scientific evidence and consensus-based processes. Referencing WHO policies that have not been endorsed by the WHA and carefully considered for their consistency with Codex principles would establish a concerning precedent and may result in a standard that is not acceptable or applicable to Codex members globally.

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the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Sodium in the [name of product] for young children

OVERVIEW

ISDI notes that CCNFSDU 38[8] agreed not to establish a maximum (85mg/100kcal) for sodium in (name of product) for young children but to state "*Sodium chloride should not be added to [name of the product] for young children*".

ISDI understands that the rationale was to increase the nutritional safety of the products by prohibiting the addition of sodium chloride, without impacting the inherent levels of sodium in cow's milk.

ISDI has considered this further and believes the decision creates mis-alignment with CAC/GL 10-1979 and other parts of CODEX STAN 156-1987. Furthermore, it does not ensure nutritional integrity, one of the key principles used to determine the mandatory composition for this category.

ISDI therefore requests CCNFSDU to reconsider the CCNFSDU38 decision and replace it with the following alternative wording: "*If sodium salts are added to the product, then the maximum sodium level should be 85 mg/100kcal.*"

CURRENT SITUATION

Sodium is inherently present in cow's milk. Most sodium in follow-up formula comes from the inherent levels; however, small quantities may be added:

1. CAC/GL 10-1979[9] permits the addition of sodium as a nutrient compound in foods for special dietary uses intended for infants and young children. Permitted sources of sodium in IF, FuF and FSMPs intended for infants, include but are not limited to sodium chloride. Permitted sources are: Sodium carbonate, Sodium hydrogen carbonate (Sodium bicarbonate), Sodium chloride, Trisodium citrate (Sodium citrate), Sodium gluconate, Sodium L-lactate, Sodium dihydrogen phosphate (Sodium phosphate, monobasic), Disodium hydrogen phosphate (Sodium phosphate, dibasic), Trisodium phosphate (Sodium phosphate, tribasic), Sodium hydroxide, Sodium sulphate. Sodium is primarily added to FuF to balance the variability in the inherent levels of sodium in cow's milk and thus ensure the production of a high quality consistent product.
2. CODEX STAN 156-1987[10] permits the addition of certain food additives to FuF (these additives have a technological need and have undergone safety assessment by JECFA). A number of food additives within the category 'pH adjusting agents' are sodium salts, i.e. Sodium hydrogen carbonate, Sodium carbonate, Sodium citrate, Sodium hydroxide.

In follow-up formula, all sources of sodium (i.e. inherent & added) must not exceed the maximum level for sodium specified in CODEX STAN 156-1987, i.e. 85 mg/100kcal.

PROBLEM/CONCERN WITH CCNFSDU38 DECISION

1. The prohibition on the use of sodium chloride is not in line with the permission provided in CAC/GL 10-1979. Nutrient compounds are included on this advisory list if they meet certain criteria, i.e. they are shown to be safe and appropriate for the intended use, they are biologically available, they comply with specific purity criteria and they are shown to be stable in the food(s) in which they are intended to be used (see section 2 of the guidelines). Furthermore, it is not clear why CCNFSDU38 singled out sodium chloride as a sodium source; however, it is assumed this was driven by discussions on sodium chloride reduction in processed foods (e.g. sauces, processed meat, bread) intended for the general population. Unlike the specialised nutrition category, sodium levels are not regulated in processed foods intended for the general population and therefore, parallels cannot be made between both categories.
2. The absence of a sodium maximum creates challenges with the following provisions from other Codex Standards and Guidelines:
    - **CAC/GL 10-1979, SECTION 1 (Preamble):** Any nutrient compound included on the advisory list must meet criteria for use stipulated in the respective standards. Therefore, if any sodium

[8] Report of the Thirty-Eighth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP17/NFSDU) – Par 104.
[9] CAC/GL 10-1979. Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children.
[10] CODEX STAN 156-1987. Codex Standard for Follow-up Formula

source is added to follow-up formula, the total sodium must meet the requirements of CODEX STAN 156-1987 (i.e. inherent & added sodium must not exceed 85mg/100kcal)

- **CODEX STAN 156-1987, SECTION 3.4.2** (**Vitamin Compounds and Mineral Salts):** The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6 (i.e. inherent & added sodium must not exceed 85mg/100kcal)
- **CODEX STAN 156-1987, SECTION 4.3 (pH-Adjusting Agents):** The amounts of sodium derived from pH adjusting agents shall be limited by good manufacturing practice and within the limit for sodium in Section 3.2.6 (i.e. inherent & added sodium must not exceed 85mg/100kcal)

3. The prohibition on the use of NaCl coupled with the absence of a maximum level for total sodium (i.e. inherent and added sodium), does not protect the nutritional integrity of the product. Furthermore, this approach is not in line with recommendations of numerous authorities across the globe to control or reduce sodium intake in children (EFSA, 2017[11]).

CONCLUSION

Based on the above, it would be more prudent to limit the maximum level of sodium in (name of product) for young children rather than ban the addition of one sodium salt (i.e. sodium chloride). This would ensure:

- Nutritional integrity and thus compliance with one of the key principles agreed at CCNFSDU38 to inform the mandatory composition of (name of product) for young children
- Consistency with the approach taken by Codex for both Infant formula and the proposed approach for Follow-up formula for older infants
- Consistency with the approach proposed by key opinion leaders (Suthutvoravut *et al.*, 2015[12]; German Society for Paediatrics and Adolescent Medicine (DGKJ), 2017[13]) on the composition of follow-up formula for young children

[11] EFSA. 2017. Draft Scientific Opinion. Dietary Reference Values for Sodium. LINK

[12] Suthutvoravut U, Abiodun PO, Chomtho S, Chongviriyaphan N, Cruchet S, Davies PS, Fuchs GJ, Gopalan S, van Goudoever JB, Nel Ede L, Scheimann A, Spolidoro JV, Tontisirin K, Wang W, Winichagoon P, Koletzko B (2015) 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*, 67(2):119-32.

[13] Koletzko B, Bührer c, JochumF, Kauth T, Körner A, Mihatsch W, Prell C, Reinehr T, Zimmer KT, Ernährungskommission der Deutschen Gesellschaft für Kinder- und Jugendmedizin e. V. 2017. Folgenahrungen für KleinkinderFolgenahrungen für Kleinkinder im Alter von einem bis 3 Jahren. (sog. Kindermilchgetränk