CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 5 **CX/NFSDU 15/37/5-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

37th Session
Bad Soden a.T. - Germany
23 – 27 November 2015

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

Comments of Argentina, Brazil, Canada, Chile, Costa Rica, Ghana, Morocco, New Zealand, Norway, Philippines, United States of America, African Union, ELC, ENSA, EUVEPRO, GOED, IDF, IFT and ISDI

ARGENTINA

1 SCOPE

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.]

Argentina agrees with the proposal under discussion.

2.1.1 ***Argentina agrees with the definition and retaining brackets) and b)***

2.1.2 **[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold].

2.1.2 Argentina agreed the previous paragraph.

~~OR~~

~~**[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] and distribution [and sale] in the country where the product is sold].~~

Argentina agrees to move 2.2 and 2.4 to other section: composition (3) and information for use (9.5)

2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 [**Older infants** means persons from the age of 6 months and not more than 12 months of age.]

2.2.3 The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months).

We *are according with the definitions for Older infants and young child.*

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS (for older infants 6-12 months)

3.1 Essential composition

is a [food] OR [product] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin~~, [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. ~~infants from the 6th month on and for young children~~.

Argentina proposes the following paragraph

Follow-up formula *is ~~a [food] OR~~* ***[product]*** *~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin~~,* ***[based on]*** *~~OR [consisting of]~~ milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been ~~[proved]~~ OR* ***[proven]*** *to be* ***[safe and]*** *~~suitable~~ [and nutritionally adequate] [to support growth and development] for ~~[the intended age range] OR~~* ***[older infants and young children]***. *~~infants from the 6th month on and for young children~~.*

[The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.]

~~OR~~

~~[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].~~

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

6.1 Overview

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal ([293 kJ]) of energy.

Argentina agrees to the correction of the Energy value kJ (293/70 Kcal) resulting to the conversion factor 4.184KJ

Argentina agrees with recommendation 1

a) Protein 2), 3), 4)

Unit	Mínimum	Máximum	GUL
g/100	kcal [1.8]	[3.5]	

Argentina agrees that the maximum protein content should be 3.5 g / 100 ml. The draft for "Infants and early childhood Formula" has taken this value.

Also agrees with the footnotes 2), 3) and 4). In relation with Note 5) we proposes to eliminate [and goats']

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

In Argentina it is only allowed cow's milk in the "Infants and early childhood Formula". The milk of other species has higher tolerance in microorganisms and somatic cells.

Note 6) Argentina support the inclusion of footnote 6, it should be retained for hydrolyzed protein formulas

b) Lipids

Argentina agrees with recommendations 4, 5, 6 and 7

c) Carbohydrates

Argentina *agrees with recommendation 7 and proposes to remove the brackets and add "maltose" and limit for precooked and / or gelatinised starches "added May be added to Infant Formula up to 30% of the total carbohydrates and up to 2 g / 100 ml" to maintain consistency with Stan IF for this population and the opinion of EFSA.*

9) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added *may be added to Infant Formula up to 30% of total carbohydrates and up to 2 g/100 ml.* [If needed, sucrose, fructose and maltose may be added provided the sum of these does not exceed ≤20% of total carbohydrate.]

6.3 Vitamin and Minerals

6.3.1

d) Vitamins

Argentina agrees with recommendation 8

Vitamin D

Unit	Minimum	Maximum	GUL
µg11) /100 kcal	~~[1.0]~~ **[2.0]**	[3.0]	-
µg11) /100 kJ	[0.24]	[0.72]	-

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

Argentina considers that the Vitamin D deficiency is common. Minimum level is in line with EU Draft Delegated Act (based on requirement of 10 µg/d with 500 kcal FUF intake) and the minimum propose is a 2. And

Argentina agrees with recommendation 10 y 11

e) Minerals and Trace Elements

Argentina agrees with recommendation 12, 13,14,15,16 17 and 18

3.3.2 Optional Ingredients

3.3.2.1 ~~In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added when required to ensure that the product [provided the product] is [safe and] suitable to form part of a [**progressively diversified diet]** OR [the complementary diet] intended for use [from 6th months on] OR [from the age of 6 months/from 6 months of age] OR [by older infants~~].

Argentina agreed with the following proposed paragraph

OR 3.3.2.1 [In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

3.3.2.2 ~~The usefulness of these nutrients shall be scientifically shown. [The suitability for the particular nutritional uses [**in products for**] of [**older**] infants and the safety of these [ingredients and] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] T the formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.]~~

Argentina agreed with the following proposed paragraph

OR 3.3.2.2 [When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect OR benefit, [taking into account levels in human milk].]

Argentina agreed with the following proposed paragraph

3.3.2.~~3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.~~ [The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added].

Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal -	12	-	
mg /100 kJ -	3	-	

Total nucleotides Levels may need to be determined by national authorities.

Docosahexaenoicacid[20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

20) If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Argentina agrees with Note 20

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	[150]
mg /100 kJ	-	-	[36]

Argentina supports the minimum and GUL established in the IF. But not agree the recommendation 19. In order to retain consistency as much as possible between the Infant Formula and Follow-up Formula Standards, its addition should be mandatory.

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	[40]
mg /100 kJ	-	-	[9.6]

Argentina supports the minimum and GUL established in the IF. But not agree the recommendation 20. In order to retain consistency as much as possible between the Infant Formula and Follow-up Formula Standards, its addition should be mandatory.

L- Carnitine

Levels may need to be determined by national authorities.

Argentina supports the minimum and GUL established in the IF. But not agree the recommendation 21. In order to retain consistency as much as possible between the Infant Formula and Follow-up Formula Standards, its addition should be mandatory.

3.3.2.4 Only L (+) lactic producing cultures may be used.

BRAZIL

GENERAL COMMENTS

Brazil appreciates the work done by New Zealand, France and Indonesia and thanks for the opportunity to present the following comments about the Review of the Standard for Follow- Up Formula (Codex Stan 156 – 1987) at step 3.

SPECIFIC COMMENTS

DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.]

2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 [**Older infants** means persons from the age of 6 months and not more than 12 months of age.]

2.2.3 The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months).

Comments: Brazil agrees with the definitions proposed for sections 2.1.1, 2.2.1, 2.2.2 and 2.2.3.

Recommendation 1

Brazil agrees with recommendation 1.

Recommendation 2

Brazil agrees with recommendation 2.

Recommendation 3

With regard to the minimum protein compositional, Brazil agrees to align with the requirements specified in the Codex Standard for Infant Formula (CODEX STAN 72-1981), i.e., 1.8g/100kcal, which is nutritionally adequate to support growth and development of older infants. According to the scientific rationale presented in the EFSA Scientific Opinion (2014)[1], this value is principally based on the evidence provided by randomised controlled

trials illustrating the adequacy of protein formulations of infant and follow-up formulae. Moreover, WHO/FAO state that the protein composition of formula will need to exceed that provided by human milk and protein requirements in order to compensate for differences in dietary protein digestibility, bioavailability and efficiency of utilization between human milk and formula to meet the protein requirements of formula-fed infants.

In relation to the maximum protein compositional requirements, Brazil understands that it should also be aligned with the requirements of CODEX STAN 72-1981, i.e., 3.0g/100kcal. We point out that the maximum value of 2.5g/100kcal would be preferable, as if an older infant was to consume 500mL/day from formula, the amount of 3.0g protein/100kcal of formula would contribute with 10g protein/day, representing approximately 66% above of the protein requirement of an infant with 6 kg b.w. Nevertheless, considering that the minimum value established for follow-up formula based on soy protein isolate is 2.25g/100kcal and in order to enable the transition to lower protein content of follow-up formula globally, Brazil supports the maximum value of 3.0g/100kcal.

Brazil agrees with the proposed wording for footnote 3.

Brazil agrees to delete footnote 6.

In relation to the use of hydrolysed protein in follow-up formula, Brazil would like to point out that the Committee should discuss it further, taking into account that the scientific evidence does not support using follow-up formula based on hydrolysed protein as an option for prevention of allergic diseases during the second half year of infancy when complementary feeding usually provides intact proteins from cow's milk and other sources (SZAJEWSKA, H; HORVATH, A.[2], 2010; BERG, A et al., 2013[3]; IEG, 2013[4]; EFSA, 2014[1]).

[1] EFSA (European Food Safety Authority). Scientific opinion on the essential composition of infant and follow- on formulae. EFSA Journal. 2014;12(7):3760.

[2] Szajewska, H.; Horvath, A. Meta-analysis of the evidence for a partially hydrolyzed 100% whey formula for the prevention of allergic diseases. Current Medical & Opinion, v. 26, n. 2, p.423-427, 2010.

[3] Berg, A. V. et al. Allergies in high-risk schoolchildren after early intervention with cow's milk protein hydrolysates: 10-year results from the German Infant Nutritional Intervention (GINI) study. J Allergy Clin Imunol, 2013.

[4] Koletzko B, Bhutta ZA, Cai W, et al. Compositional requirements of follow-up formula for use in infancy: Recommendations of an international expert group coordinated by the early nutrition academy. Ann Nutr Metab. 2013;62:44-5.

Hence, there would not be a justification for using hydrolysed protein in follow-up formula intended for healthy older infants. Based on the scientific rationale, Brasil considers that the Committee should discuss the use of hydrolysed protein in a specific standard for formulas for special medical purposes intended for older infants.

Recommendation 4

Brazil agrees with recommendation 4.

Recommendation 5

Brazil agrees with recommendation 5.

Recommendation 6

Brazil agrees with recommendation 6.

Recommendation 7

Brazil agrees with the proposed minimum and maximum carbohydrates compositional requirements. We also suggest establishing a minimum lactose content of 4.5 g/100 kcal (EFSA, 2014[5]).

Brazil does not support the addition of honey whether raw or pasteurized as it is not recommended for consumption by infants aged 0-12 months. We understand that the addition of sucrose and fructose in

follow-up formula should be avoided. According to the EFSA scientific opinion (2014)[5], the consumption of these carbohydrates by healthy infants does not have any advantages over the consumption of lactose and may, because of their greater sweetness, increase the preference for sweet tastes in infants. However, according to the industry, the use of sucrose may be necessary due to technological reasons, as for example in the micro-encapsulation of polyunsaturated fatty acids added to infant formula. Thus, its voluntary addition may only be permitted under specific situations.

With regard to the use of hydrolysed protein in follow up formula, we reiterate the comments provided to "Recommendation 3".

Therefore, Brazil suggests the following wording for footnote 9:

9) ~~Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.~~ **The amount of lactose shall be at least 4.5g/100 kcal. This provision shall not apply to follow-up formulae in which soya protein isolates represent more than 50 % of the total protein content.** Only precooked and/or gelatinised starches gluten-free by nature may be added. [~~If needed,~~ Sucrose~~, fructose~~ may be added ~~provided the sum of these does not exceed ≤20% of total carbohydrate~~ **to follow up formula when technologically justified. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content.**]

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5 EFSA (European Food Safety Authority). Scientific opinion on the essential composition of infant and follow- on formulae. EFSA Journal. 2014;12(7):3760

Recommendation 8

Brazil is in favour of lowering the maximum level of vitamin A to 114 µg/100 kcal, because an intake of 500 kcal per day at a maximum of 225, 180 or 140 µg/100 kcal would exceed the UL for vitamin A for infants from 7-12 months (600 µg/d; IOM, 2001[6]).

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6 Institute of Medicine 2001 Dietary reference intakes for calcium and vitamin D. Washington, DC: The National Academies Press.

Recommendation 9

Brazil agrees with the proposed minimum and maximum levels for vitamin D.

Recommendation 10

Brazil agrees with the proposed minimum and GUL values for vitamin B_6.

Recommendation 11

Brazil agrees with the proposed minimum and GUL values for folic acid.

Recommendation 12

Brazil agrees with the proposed minimum and maximum values for iron.

Recommendation 13

Brazil agrees with:

- the minimum and GUL values proposed for calcium;
- the GUL value proposed for phosphorus; and
- the ratio calcium/phosphorus.

In relation to the minimum value proposed for phosphorus, we point out that if an older infant was to consume 500kcal/day from follow-up formula, the amount of 25mg/100kcal would not meet the dietary reference intake of 275mg/day for infants from 7-12 months (IOM, 2004[7]). Thus, Brazil suggests the minimum value of 60mg/100kcal.

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7 Institute of Medicine 2004 Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. Washington, DC: The National Academies Press.

Recommendation 14

Brazil agrees with the proposed minimum and GUL values for manganese.

Recommendation 15

Brazil agrees with the proposed minimum and GUL values for iodine.

Recommendation 16

Brazil agrees with the proposed minimum and GUL values for selenium.

Recommendation 17

Brazil agrees with the proposed minimum and GUL values for copper.

Recommendation 18

With regard to the GUL for zinc, we point out that the consumption of 500 kcal/day of formula at 1.0mg/100kcal would reach the tolerable upper level of 5mg established by IOM (2004[8]) for older infants.

[8] Institute of Medicine 2004 Dietary Reference Intakes for zinc. Washington, DC: The National Academies Press.

Recommandation 19

Brazil agrees to include choline in the Optional Ingredients section of the Follow-up Formula Standard for product for older infants. With regard to the GUL, Brazil suggests aligning with the requirements specified in the Codex Standard for Infant Formula (CODEX STAN 72- 1981), i.e., 50mg/100kcal. Although there is no UL established for choline for infants from 7 to 12 months, if an older infant was to consume 500kcal/day from formula, the GUL of 150mg/100kcal would contribute with a daily consumption of 750mg of choline which represents five times the dietary reference intake of 150mg/day (IOM, 2001[9]). We understand that there is no need to add a substance in an amount that would exceed five times the requirement.

[9] Institute of Medicine 2001 Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline 2004. Washington, DC: The National Academies Press.

Recommendation 20

Brazil agrees to include myo-inositol in the Optional Ingredients section of the Follow-up Formula Standard for product for older infants and with the GUL of 40mg/100kcal.

Recommendation 21

Brazil suggests establishing the GUL of 2mg/100kcal for L-carnitine based on the upper end of the usual range found in human milk (Koletzko et al., 2005[10]).

[10] Koletzko et al., Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group, 2005.

7. OPTIONAL INGREDIENTS FOR OLDER INFANTS (6-12 MONTHS)

Recommendation 22

3.2 Optional Ingredients

3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added ~~when required~~ to ~~ensure that~~ the product [provided the product] is [**safe and**] suitable to form part of a [**progressively diversified diet**] OR [**the complementary diet**] intended for use [**from 6th months on**] OR [**from the age of 6 months/from 6 months of age**] OR [**by older infants**].*

OR

[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

Comments

Brazil is in favour of the second text proposed for section 3.3.2.1. We suggest including a reference for "complementary feeding diet", as follows:

[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient ***as part of a complementary feeding diet****, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]*

3322 ~~The usefulness of these nutrients shall be scientifically shown.~~ *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~, taking into account levels in human milk~~.]*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit, [taking into account levels in human milk].]*

Comments

Brazil is in favour of the second option with some amendments as follows:

*[When any of these nutrients or substances is added, the formula shall contain significant amounts to achieve the intended effect OR benefit, ~~[taking into account levels in human milk]~~ [**based on the requirements of older infants**]].*

We think that the amounts of other optional ingredients added to follow-up formula should be based on the requirements of older infants.

3323 ~~When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.~~ [*The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not*

intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added].

Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid[20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

20) If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Comments

Brazil agrees with the texts and criteria proposed for section 3.3.2.3.

3.3.2.4 Only L(+) lactic producing cultures may be used.

For clear guidance, Brazil considers important to set specific requirements for the addition of L(+) lactic producing cultures in formulae intended for infants. As L(+) lactic producing cultures are naturally sensitive to heat, we think that there should be a specific provision requiring that the follow-up formula ready for consumption should contain significant amounts of viable bacteria considering the safe dilution temperature for preparation of powdered infant formulae recommended by FAO/WHO (2007) and by Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (2008). Thus, we suggest the following text for further discussion:

3.3.2.4 Only L(+)lactic acid producing cultures may be used. **The safety and purpose of the strains shall be scientifically demonstrated, preferably, through systematic review of clinical trials. When added, the following requirements shall also be taken into account:**

The strain identity shall be in accordance with the International Committee on Systematic Bacteriology.

The follow up formula prepared ready for consumption shall contain significant amounts of the viable bacteria, considering the safe dilution temperature recommended by FAO/WHO* and Codex publications.**

*** Safe preparation, storage and handling of powdered infant formula – Guidelines, 2007.**

**** CAC/RCP 2008. Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.**

We think that the Committee should also discuss a provision regarding the addition of oligosaccharides in formulae intended for infants as these products are currently available in the market. We suggest the following text for further discussion:

> ***[Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow up formulae. In that case their content shall not exceed 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl- saccharose. Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with the sections 3.3.2.1, 3.3.2.2 e 3.3.2.3]***
>
> (Reference: COMMISSION DIRECTIVE 2006/141/EC; EFSA, 2014).

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

8.2 Option for consideration

Brazil supports the approach presented in the section 8.2 as a starting point for discussion and consideration by the Committee. We highlight the importance of specific requirements regarding the prohibition of adding sugars and trans fatty acid in these products.

CANADA

GENERAL COMMENTS

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

Canada believes (with a few exceptions, due to new data) that the composition of FUF for older infants should be as close as possible to the infant formula standard, since this was fairly recently revised, and that the products for older infants should be similar, in order to meet the needs of this age group. For FUF for young children, Canada does not support option 1 that uses the essential composition of formula for older infants as a starting point for FUF for young children, as we believe that a less nutrient dense product, using cow milk as a model (option 2), is more appropriate for young children eating a varied diet.

SPECIFIC COMMENTS:

5. DESCRIPTION OF FOLLOW-UP FORMULA

Based on the collective comments of the 2015 eWG, the Chairs propose the following structure and definitions for Section 2 of the Standard for Follow-up Formula (CODEX STAN 156-1987) for consideration by the Committee:

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.**]**

2.1.2 **[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold**].**

OR

[Follow-up formula is so processed ~~by physical means only~~ and ~~so~~ packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] ~~and~~ distribution [and sale] ~~in the country where the product is sold~~**].**

2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 **[Older infants** means persons from the age of 6 months and not more than 12 months of age.**]**

2.2.3 The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months).

Specific Comments from Canada

Canada agrees to the alignment of the structure and terminology within Section 2: Description, with the equivalent section of the IF standard. Canada proposes that the definition of 'complementary feeding' from section 3.4 of the Codex Guidelines on Formulated Complementary Foods for Older Infants and Young Children should be included in the FUF standard?

Canada is proposing changes to 2.1.1 and 2.1.2, please see the suggested wording in the box below.

Suggested wording from Canada:

2.1.1 Follow-up formula means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) ~~the~~ [a] liquid part of the diet for older infants when complementary feeding is introduced; and

b) [may be used as part of [~~a~~] the] liquid part of the progressively diversified diet of young children.]

- 2.1.2 [Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution **~~in the country where the product is sold~~].**

Text previously appearing in section 2.2 was moved to section 3.1.1, under Essential Composition, but amended wording was proposed by the Chair as follows:

Follow-up formula is a [food] OR [product] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,~~ [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. ~~infants from the 6th month on and for young children.~~

Canada proposes the following revised wording:

Follow-up formula is a [food] ~~OR~~ [~~product~~] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,~~ [based on] ~~OR [consisting of]~~ milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been ~~[proved] OR~~ [proven] to be [safe and] ,suitable ~~[and nutritionally adequate]~~ [to support growth and development] for ~~[the intended age range] OR~~ [older infants and young children]. ~~infants from the 6th month on and for young children.~~

Rationale and Comments from Canada:

Canada notes that there will likely be discussion around whether all three wordings 'safe', 'suitable' and 'nutritionally adequate' are needed in the statement. We are of the opinion that these three have different meanings. In addition, we are of the opinion that the testing of nutritional adequacy using a clinical growth and tolerance studies are not generally feasible for FUF for older infants and young children and should therefore not be retained. From 6 months of age, complementary foods are introduced which makes clinical testing problematic.

In Canada, we require clinical growth and tolerance studies for new infant formulas such as those with an ingredient not previously included in infant formula in Canada, or manufactured in a new facility or by a manufacturer that is new to Canada; formulas with major changes in energy density, sources and levels of macronutrients, iron and calcium may also require clinical testing. In Canada, manufacturers clear their infant formulas through a pre-market notification process, and carry out clinical growth and tolerance studies on infants aged from 0-14 days to about 4 months, with the product used as a sole source of nutrition. This is because nutrient requirements are greatest during the first 8 weeks of life.

In Canada, the FUF formulas which have been allowed to enter the market are similar to the same manufacturer's starter formula, with perhaps the only changes being different milk ingredients, and more iron and calcium. The safety of FUF for older infants with a similar composition to the starter formula can then be supported. In summary, we do not know of a way to appropriately assess a product only produced for older infants or young children.

6. COMPOSITION OF FUF FOR OLDER INFANTS (6-12 MONTHS)

Recommendation 1

Canada agrees with recommendation 1

Recommendation 2

Canada agrees with recommendation 2

Recommendation 3

Canada disagrees with the recommended maximum of 3.5 g/100 kcal and proposes to align the protein maximum level for FUF with the IF Standard at 3.0 g/100kcal, as this is an established safe level for infants up to 12 months of age. There is no evidence of a physiological need for protein intakes higher than 3.0 g/100 kcal in infancy (except for preterm and VLBW infants), which is the currently permitted maximum content of protein in IF in most jurisdictions. In addition, protein intakes of infants are generally well above the requirements (European Food Safety Authority (EFSA) Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA panel on Dietetic Products, Nutrition and Allergy. EFSA Journal 2014; 12 (7); 3760). Further, high infant milk protein intakes during the first year of life that markedly exceed metabolic requirements were shown to lead to excessive weight gain which can increase the risk of later obesity and associated diseases. (Koletzko B et al. Compositional Requirements of Follow-Up Formula for Use in Infancy: Recommendations of an International Expert Group Coordinated by the Early Nutrition academy. Annals of Nutrition and Metabolism 2013;62: 44-54). Canada supports having a transition period for industry to adapt to this lower protein level.

Canada agrees to include footnote 2, as stated in the IF standard.

Canada agrees to remove the amino acid ratios from footnote 3. Canada would like to highlight that there is the concern that a high ratio of methionine to cysteine may negatively affect the nutritional quality of the infant formula, which has been shown at least in rats. (G. Sarwar, R.W. Peace, H.G. Botting, Dietary cysteine/methionine ratios and taurine supplementation: effects on rat growth, amino acids and bile acids, Nutrition Research, Volume 11, Issue 4, April 1991, Pages 355-363, ISSN 0271-5317, http://www.sciencedirect.com/science/article/pii/S0271531705803112)

Canada agrees to change the wording of footnote 4 from “Infant Formula” to “follow-up-formula”

Canada agrees that footnote 5 should be retained, but with the following wording change in the second sentence:

The minimum value applies to cows’ **[and goats’]** milk protein. For ~~infant~~ follow-up formula based on non-cows’ milk **[or non-goats’ milk]** protein other minimum values may need to be applied. For ~~infant~~ follow-up formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

Canada agrees that footnote 6 be removed as older infants are consuming complementary foods supplying protein and there is less concern about protein content and quality.

Please note that the units used to express protein levels should be **g/100kcal**, and not **mg/100kcal.** Also, the superscript to a previous footnote inserted in the protein units (mg[10] /100 kcal, (mg[10] /100 kJ) should be removed.

Recommendation 4:

Canada agrees with recommendation 4.

Please note that there is a superscript to a footnote inserted in the total fat units (mg [10] /100 kcal, mg [10] /100 kJ) which should not appear in the total fat section.

Recommendation 5

Canada agrees with recommendation 5

Recommendation 6

Canada agrees with recommendation 6.

The footnote under 3.3.2 in the Optional Ingredients section concerning DHA, ARA and EPA should be retained. **Please note:** The content of EPA which can occur in sources of LC-PUFAs, should not exceed the content of DHA (this is also covered within Footnote 20 from Recommendation 22).

Recommendation 7

Canada agrees to align the total carbohydrate requirements of the IF and FUF standards.

Canada agrees with footnote 9. Canada would also like to highlight that in North America soy-based formulas may contain glucose polymers as sucrose (corn maltodextrin may be listed as an ingredient – another form of a glucose polymer).

Canada agrees that as a precautionary approach FUF for 6-12 months should not contain gluten.

Canada agrees with the decision to remove honey as a suitable carbohydrate source.

Please note that the units used to express carbohydrate levels should be **g/100kcal** and not **mg/100kcal.**

Recommendation 8

Canada agrees with recommendation 8.

Recommendation 9

Canada agrees to aligning with the minimum vitamin D level as stated in the IF standard, 1.0 µg/100kcal, and with the rounding change.

Canada agrees to the maximum vitamin D level of 3.0 µg/100kcal to allow for regional variation and requirements.

Recommendation 10

Canada agrees with the proposed minimum and GUL values for vitamin B6 and does not object to the removal of the footnote, to align with the IF standard.

Recommendation 11

Canada agrees with the proposed minimum and GUL values for folic acid and does not object to using folic acid for FUF for older infants to align with the IF standard.

Recommendation 12

Canada agrees with retaining the iron minimum value currently used in the FUF standard (1.0 mg/100kcal).

Canada does not agree with retaining the iron maximum level currently used in FUF standard (2.0 mg/100kcal). Canada is taking a precautionary approach and recommends a maximum level of iron of 1.5 mg/100 kcal, pending stronger evidence. Our previous concerns regarding the potential long-term adverse effects of high intakes of iron early in life have recently been echoed in the Journal of Pediatrics: http://www.jpeds.com/issue/S0022-3476(15)X0002-3

Our second option, in view of the large variation in iron status around the globe, is that Canada would agree to adding a footnote to the GUL column, the same as is present in the IF standard, stating: “Levels may be determined by National Authorities”.

Canada agrees with footnote 17 for having separate minimums and maximums established for formula based on soy-protein to take into account potentially lower absorption efficiency of iron compared to that from cow’s milk protein based formula.

Recommendation 13

Calcium:

Canada agrees with the adoption of the minimum calcium level of 50mg/100kcal and the minimum phosphorus level of 25mg/100kcal as well as the calcium to phosphorus ratio.

Canada does not object to the revised calcium GUL of 180 mg/100 kcal (from 140 mg/100 kcal in the IF standard) since this would not increase calcium intakes above the IOM UL of 1500mg/day for infants aged 6-12 months consuming 750ml per day of FUF.

Phosphorus:

Since a GUL for phosphorus is to be established for the first time, **Canada supports the inclusion of footnote 18 from the IF standard**, which states: **“This GUL should accommodate higher needs with soy formula”** due to the different phosphorus absorbency seen in soy formula.

Canada agrees with the phosphorus GUL of 100mg/100kcal. We note that a GUL for phosphorus is proposed for the first time, as appears in the codex IF standard. It is also important, therefore, to retain the same ratio of calcium to phosphorus in the FUF standard.

Recommendation 14

Canada agrees with recommendation 14.

Recommendation 15

Canada agrees with recommendation 15.

Recommendation 16

Canada agrees with recommendation 16.

Recommendation 17

Canada agrees with recommendation 17.

Recommendation 18

Canada agrees with recommendation 18.

Recommendation 19

Canada disagrees with recommendation 19**.** Canada supports the mandatory addition of choline as per the IF standard as a precautionary approach. The IEG (2013) notes that the minimum choline content of 7 mg/100 kcal set for IF is also recommended for FUF.

Recommendation 20

Canada disagrees with recommendation 20. Canada supports the mandatory addition of myo-inositol with a minimum of 4 mg/100kcal and a maximum of 40 mg/100kcal (LSRO 1998), to align with the IF standard, Canada supports the mandatory addition as a precautionary approach. Concentrations of myo-inositol were found to be significantly higher in breast milk than in formula milk (Cavalli C, Teng C, Battaglia FC and Bevilacqua G, 2006. Free sugar and sugar alcohol concentrations in human breast milk. Journal of Pediatric Gastroenterology and Nutrition, 42, 215-221)

Recommendation 21

Canada disagrees with recommendation 21. The LSRO 1998 recommend a minimum carnitine content of infant formula of 1.2 mg/100kcal, a level similar to that found in human milk, as a precautionary approach. EFSA recommends that a minimum L-carnitine content should be set for IF based on milk protein. Canada recommends the same minimum amount for FUF as is currently in the IF standard, 1.2 mg/100 kcal.

7. OPTIONAL INGREDIENTS FOR OLDER INFANTS (6-12 MONTHS)

Recommendation 22

For 3.3.2.1, Canada prefers the second proposed text option, as follows:

> *[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]*

For 3.3.2.2, Canada agrees with option 1 because the paragraph discusses suitability as well as safety assessments, as follows:

> ~~The usefulness of these nutrients shall be scientifically shown.~~ *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~, taking into account levels in human milk~~.]*

For 3.3.2.3, Canada agrees with the text as revised.

Canada suggests that if the committee decides not to make DHA mandatory for FUF, then discussion on levels should be carried out under recommendation 22 – optional ingredients.

Canada agrees with the inclusion of footnote 20 concerning DHA, ARA and EPA, as stated in the IF standard. **Please note** that the content of EPA which can occur in sources of LC-PUFAs, should not exceed the content of DHA.

8. ESSENTIAL COMPOSITION OF FUF FOR YOUNG CHILDREN (12-36 MONTHS)

8.1.1 Flexibility:

Canada agrees with flexibility for the addition of nutrients. Canada agrees that nutrient needs vary between countries, supplement programs and food fortification practices, so flexibility in the compositional requirements for certain nutrients in follow-up formula for young children should be allowed for. We support flexibility for individual countries based on their key nutrients of concern.

8.1.2 Less Prescription

Canada agrees with a less prescriptive approach. Canada agrees that compared to the compositional requirements of formula for older infants, follow-up-formula for the 12-36 month age group does not need to contain the full range of nutrients that are contained in products for older infants.

8.1.3 Consistency (as much as possible) with follow-up-formula for older infants

Canada does not agree with basing FUF for young children on the nutrient dense products for FUF for older infants as indicated in our CP1/CP2 position.

Canada supported Option 2, proposing using cows' milk as a model for the composition of products for young children. We consider that FUF for older infants is not the best model for young children since it is a nutrient dense product, which would not be nutritionally necessary or generally appropriate for young children eating a varied diet. Canadian young children 12 to 36 months of age consume an average of 455 ml cows' milk/day (CCHS 2004). This information can guide the base composition of FUF for young children given that the average daily amount of cows' milk consumed in Canada is comparable to the amount of milk needed by young children to meet the nutrient needs of this population (WHO Guiding Principles for feeding non-breastfed children 6-24 months of age.)

8.1.4 Key Nutrients

Canada agrees with the derivation of minimum levels for the essential fatty acid ALA, and DHA when added, since the WHO/FAO Expert Consultation on Fats and Fatty Acids in Human Nutrition (2008) identified an increasing interest in the quality of dietary fat in early life as a major determinant of growth.

Canada agrees that DHA should be an optional ingredient for FUF for 12-36 months and that a minimum level should be derived. If DHA is added ARA should also be added in similar proportions to those stated when DHA and ARA are added to FUF for older infants (6-12 months). The content of EPA, which can be present in sources of LC-PUFAs, should not exceed the content of DHA.

Canada considers that minimum compositional requirements for iron will be required but also that the level of iron to be added and its bioavailability should be considered to avoid potential irreversible long-term adverse effects of iron deficiency or iron deficiency anaemia. However, excess iron in iron-replete young children can have adverse effects, and mandating even a minimum level of iron in FUF could exacerbate these effects in some young children. Canada is looking at new research on iron in young infants (Supplement in the Journal of Pediatrics (October) on iron for infants). Canada previously sent the eWG a summary report of iron supplementation in iron-replete infants. Canada would support the addition of iron if minimum and maximum levels can be established. **Canada emphasizes that a maximum iron content should be incorporated**

Canada agrees that nutritional equivalence to cows' milk is important, hence the Standard should include adequate levels of those key nutrients present in cows' milk such as calcium, riboflavin, vitamins B12, A, D, and Zinc. In Canada, cows' milk is fortified with vitamin D at 300-400 IU/reasonable daily intake. Canada notes that other key nutrients present in cow's milk are potassium, phosphorus and magnesium.

Canada does not agree that equivalence with the Infant Formula Standard is important. The product would not be considered a breast milk substitute.

8.1.5 Nutritional Integrity

Canada believes further discussion is required and that the first step would be to determine options for moving forward and determining the role of this type of product in diets of young children. EFSA is currently doing an evaluation of the composition of young child formula (from ages 1-3 years) based on European data. Their recommendations could inform these discussions

8.1.6 Other Issues

For the purposes of the Agenda paper the Chairs have referred to products targeted to young children aged 12-36 mo. as *follow-up formula for young children*. Canada has proposed young child milk-based beverage – this ties in with the non-necessity of this product for the majority of children in this age group.

8.2 Options for Consideration

The chairs recommend that the composition of follow-up formula for young children (12-36 months) shall be presented as a narrow list of mandatory nutrients with the option of national authorities requiring additional mandatory nutrients based on the nutritional needs of their population. **Canada agrees with the chairs recommendation.** The role and use of follow-up-formula for young children varies across countries and regions, therefore it is not necessary for all nutrients to be mandatory. An approach which allows considerable flexibility in the compositional requirements of formulas for young children will allow countries to establish their own limits (minimums and maximums) and determine key nutrients for young children.

Codex Requirement- mandatory additions

The chairs have suggested that the core composition of FUF for young children will include:

- Protein
- Fat – consider the fatty acid profile, including parameters for ALA and LA and maximum limits for trans fatty acids and saturated fatty acids
- Carbohydrate – based on residual energy after fat and protein contribution has been calculated. Consider including a limit for the addition of sugar
- Iron
- Calcium
- Vitamin A

Canada proposes further discussion on mandatory nutrients. Canada proposes the mandatory addition of vitamin D, which is not in the above list, and more flexibility. In particular, Canada proposes that the effect of mandatory nutrients on bioavailability of other nutrients be considered (e.g. calcium could decrease the uptake of other mineral nutrients and trace elements). If there is mandatory addition of iron to FUF for young children, the maximum amount decided on should be based on the new research available.

Codex requirement – voluntary additions

The chairs recommended that in addition to those mandatory nutrients listed above, other vitamins and minerals listed for addition to follow-up formula for older infants may be added to follow-up formula for young children on a voluntary basis and that the level of addition shall meet the requirements stipulated for follow-up formula for older infants.

Canada has previously stated, and we maintain, that using the nutrient composition of FUF for older infants should not be applied or extrapolated to FUF for young children. In addition the balance of mandated and voluntarily added nutrients must be carefully considered by each country to ensure that the formula is nutritionally appropriate.

Codex requirement – Optional Ingredients

Chairs propose that further to the mandatory and voluntary nutrient additions, other ingredients or substances may be added to FUF for young children as per the optional ingredient principles established for FUF for older infants. Canada has previously stated, and we maintain that using the nutrient composition of FUF for older infants should not be applied or extrapolated to FUF for young children without careful consideration.

National Authority discretion

The chairs propose that in addition to those provisions stated above, national authorities may require further nutrients be mandated for addition to follow-up formula for young children to meet the nutritional needs of their population. These nutrients can be chosen from the essential compositional requirements for follow-up formula for older infants, in which case the level of addition shall meet the requirements stipulated in that Standard.

Canada proposes further discussion on this issue in particular, as stated previously, we do not agree with using the level of addition of nutrients stipulated in the standard for FUF for older infants, for young children.

CHILE

Recommendation 1

We agree with this recommendation.

Recommendation 2

We agree with this recommendation.

Recommendation 3

We agree with the maximum value (3.5 g/100 kcal). And we propose a minimum value of 1.65 g/100 kcal, given that recent estimations for protein requirements are lower than previous ones, mainly because of changes made to the reference body weight used in the past (WHO/FAO/UNU 2007).

Furthermore, the composition of breast milk changes throughout the first year of lactation. Protein content decreases significantly after six months (1.08–1.20 g/100 kcal), (IEG 2013).

Some studies suggest that an excessive protein intake in early childhood may be associated with growth alterations and the risk of obesity in later life. ENA recommends setting the minimum protein content of cow's milk in the follow-up formula at 1.65 g/100 kcal, based on high-quality proteins.

The eWG previously established 450 mL of FUF/day to be an adequate intake. Based on this intake, while taking into account the protein level of 1.65 g/100 kcal proposed by the ENA and an energy density of 67 kcal/100 mL, then the FUF provides 5.0 g of protein/day with 302 kcal. This is equivalent to 49–52% of the recommended daily protein requirement for 6-month-old infants. It must be noted that at this age the FUF is part of an increasingly varied diet, which includes other protein sources, such as meat and fish, among others.

If protein consumption is calculated based on the recommended value (PRI, Population Reference Intakes) for daily protein intake, then it is equivalent to 1.31 g of protein/kg of body weight at the age of 6 months (WHO 2007). A value equal to 1.64 g/100 kcal was obtained using a daily energy consumption of 80 kcal/kg, (WHO/FAO, human energy requirements, 2004). This value is very similar to that recommended by ENA.

With regards to the footnotes:

No. 2: We agree with this proposal.

No. 3: We agree with this proposal.

No. 4: We agree with this proposal.

No. 5: We agree with this proposal.

No. 6: We propose that:

- Formulas based on hydrolysed proteins containing less than 2.25 g of protein/100 kcal, and

- Formulas based on non-hydrolysed milk protein from other breeds of cow (or goat) should be clinically evaluated.

Recommendation 4

We agree with this recommendation.

Recommendation 5

We agree with this recommendation.

Recommendation 6

We support the mandatory addition of DHA and ARA in Follow-up Formula.

Both these fatty acids are components of breast milk, the standard reference comparison for the compositional requirements. As is the case for DHA, ARA is always found at stable levels in breast milk, even when the mother's nutritional status is poor, demonstrating the biological importance of ARA for the child's health and development. With regards to combined DHA and ARA, FAO experts conclude that, "... due to their essential role in the normal development of the retina and brain in human beings, they must be considered as conditionally essential in early development".

As noted by the Working Group, the intake of complementary foods does not provide sufficient quantities of DHA or ARA intake for older infants and small children in the majority of developing countries, as demonstrated in an article in the Exponent project's journal. ARA is formed from its precursor LA in a process similar to the one which produces DHA from ALA. Even in healthy children, Carnielli et al. show that by 7 months the child's capacity for endogenous synthesis of DHA and ARA declines dramatically compared with that at birth (2007) and evidence supports the need for additional intake of both LA and ARA to maintain plasma concentrations and fatty acids to replace fat stores (Pawlosky et al., 2006). Both pathways are competing with the same enzymes, in an effort to maintain a balance between n-3 and n-6 PUFA and related eicosanoids, and it is therefore important that DHA and ARA are added to formulas in a balanced fashion.

In the current Standard Infant Formula, DHA and ARA are non-independent optional ingredients which must be considered simultaneously. Specifically, the Standard states that, "If docosahexaenoic acid (22: 6 n-3) is added to the infant formula, then arachidonic acid (20: 4 n-6) must be added to at least the same concentration as DHA. The eicosapentaenoic acid content (20: 5 n-3) must not exceed the docosahexaenoic acid content, which can occur in some LC-PUFA sources". There is presently no scientific evidence that has raised questions about the need to include ARA whenever DHA is added.

The Standard for Infants does not establish a minimum level of DHA.

Some regulatory agencies across the world require the minimum level of DHA in infant formula to be 0.2% of the total fatty acid content. If the product makes claims about visual benefits, then 0.3% DHA must be added.

Recommendation 7

We agree with this recommendation.

Recommendation 8

We agree with this recommendation.

Recommendation 9

We propose a minimum value of 2.0 µg/100 Kcal (EFSA) and a maximum value of 4.5 µg/100 Kcal (IEG), due to a world-wide vitamin D deficiency and taking into account recent scientific recommendations for higher levels. These levels allow each country greater freedom to adapt the EFSA value, within a safe range.

With regards to the note, we propose that only vitamin D3 (cholecalciferol) is recommended as its greater biological activity has been demonstrated and it is the natural form synthesized by the human body.

Recommendation 10

We agree with the maximum and minimum values.

But we suggest including the following note:

Formulas must contain a minimum of 15 mg of vitamin B6/g of protein, even when the minimum of 35 µg/100 kcal has been reached.

Recommendation 11

We agree with this recommendation. Furthermore, for the purposes of content analysis, we recommend considering the food's natural folate content plus the added folic acid content, according to the corresponding conversion factors:

1 µg food folate = 0.6 µg folic acid.

Recommendation 12

We agree with this recommendation.

Recommendation 13

We propose to maintain the current minimum values for Ca and P, i.e.:

Ca: min. 90 mg/100 kcal

P: min. 60 mg/100 kcal

Furthermore, we agree with the GUL and the Ca:P ratio proposed in this recommendation.

Recommendation 14

We agree with this recommendation.

Recommendation 15

We agree with this recommendation.

Recommendation 16

We agree with this recommendation.

Recommendation 17

We agree with this recommendation.

Recommendation 18

We agree with this recommendation.

Recommendation 19

See comment in recommendation 22

Recommendation 20

See comment in recommendation 22

Recommendation 21

See comment in recommendation 22

Recommendation 22

We agree with this recommendation.

We propose that the addition is voluntary, yet when additions are made they should comply with established ranges, including a minimum, maximum and a GUL.

If there are no values, we propose that it remain pending for further review.

For section 3.3.2, we support the following texts:

3.3.2.1, we support proposals in the second paragraph. (*In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or*

substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence)

3.3.2.2 We support option 2. (*When any of these ingredients or substances are added, the formula shall contain sufficient amounts to achieve the intended benefit, taking into account levels in human milk.)*

3.3.2.3 we support the text proposed and its amendments, apart from:

1: the addition of optional DHA, as we believe it should be mandatory.

2: Furthermore, ingredients should have a minimum value, to ensure the desired benefit, as well as a maximum or GUL.

COSTA RICA

General comments

Costa Rica considers that eWG should propose to use the same approach that was decided in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, where the Scope articulates the application of the WHO International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, as well as applicable World Health Assembly Resolutions.

Costa Rica agree that further in the discussion the labelling should contain the necessary information about the correct use of the product and labelling statements like "FUF is not a breast-milk substitute and should not be recommended for use with infants below 6 months of age" can be evaluated.

The Scope of the Follow up Formula can also be amended with the inclusion of the part of section 1.4 of CODEX STAN 72-1981, revision 2006 "The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981) and the Global Strategy for Infant and Young Child Feeding".

At this step of discussion, it has to be noted that the terms of reference agreed during the last CCNFSDU do not refer to labelling & scope therefore this topic is not to be addressed at this time.

We also consider it should be clarified in the scope, when the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013) are applicable to FUF for young children.

Specific comments:

Description of follow up formula (section 2)

2.1 Product Definition

2.1.1 a) Costa Rica agrees with chairs proposal and only suggests to change an “a” instead of “the” at the beggining of the sentence, to be read as follows:

… [a) a ~~the~~ liquid part of the diet for older infants when complementary feeding is introduced; and…

2.1.2 Costa Rica agrees with the second chairs proposal:

Follow-up formula is so processed ~~by physical means only~~ and ~~so~~ packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] ~~and~~ distribution

[and sale] ~~in the country where the product is sold~~].

2.2 Other definitions

Costa Rica agrees with the proposed definitions for 2.2.1, 2.2.2 y 2.2.3.

Costa Rica agrees with chairs proposal to move 2.2 to section 3 Essential Composition and 2.4 to section 9.5 Information for use.

Text in 2.2 should read as:

Follow-up formula is a [food] ~~OR [product] prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin~~, [based on] ~~OR [consisting of]~~ milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally

adequate] [to support growth and development] for ~~[the intended age range] OR~~ [older infants and young children]. ~~infants from the 6th month on and for young children.~~

Recommendation 1

Costa Rica supports recommendation 1.

Recommendation 2

Costa Rica supports recommendation 2.

Recommendation 3

Regarding this recommendation, Costa Rica supports a mínimum protein content of 1.65 g/100 kcal.

Some authorities have lowered protein requirements for infants and young children over the last decade (WHO/FAO/UNU, 2007; EFSA, 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 were lowered to 1.65 g/100 kcal based on metabolic requirements (Koletzko, 2013). There should be considered to include requirements for protein hydrolysates, the minimum limit of 1.8g shall be adopted for follow-up formula.

We support the Chair's Proposal for a Maximum Protein level in FUF 6-12mo of 3.5 g protein/ 100kcal.

The proposed upper level of protein of 3.5 g/100 kcal would provide 14% of total energy provided from protein. This falls within the range of protein typically and safely consumed for 6-12 month infants within Europe which is reported to be around 10-15% of total energy (Lagström et al., 1997; Noble and Emmett, 2001; Hilbig, 2005; de Boer et al., 2006; DGE, 2008; Fantino and Gourmet, 2008; Marriott et al., 2008; Thorsdottir et al., 2008; Lennox et al., 2013; IN EFSA 2014). In the US, Butte et al. (2010) found that protein intake as a percentage of energy increased with age in the Feeding Infants and Toddlers Study (FITS), and that intakes were within the IOM (2002) Acceptable Macronutrient Distribution Range (AMDR) of 5-20% of energy. The range of protein intakes in US infants 6 to 11months was wider at 7-13% of energy (for 10th and 90th percentiles respectively) compared to that reported for older infants 6 to 12 months in Europe.

We would suggest rewording footnote 6 once the minimum protein content is established.

Recommendation 4

Costa Rica supports recommendation 4.

Recommendation 5

Costa Rica supports recommendation 5.

Recommendation 6

Costa Rica supports recommendation 6.

Recommendation 7

Costa Rica supports recommendation 7.

Recommendation 8

Costa Rica supports the minimun to be aligned with IF Standard. However the maximum should be based on current FuF standard and on UL of 1000 µg/d (UK Committee on Toxicity) with 700 kcal FuF intake.

The nutrient stability of vitamin A over infant formula over shelf life was previously reported to be ≥25% and analysis of vitamin A is also subject to significant intra and interlaboratory variability (Maclean et al, 2010). A wider range is required to be technically feasible in practice.

Furthermore, there is no evidence of harm or concern with the existing maximum of 225ug RE/ 100kcal. The permitted range for vitamin A should continue to be at least 3 times the minimum as currently applies for both Codex Stan 156-1987 and Codex Stan 72-1981.

Recommendation 9

Costa Rica supported setting the minimum vitamin D level based on the recent recommendation proposed by EFSA (2014). This level (2 µg/100 kcal) corresponds to the need to respond to the low vitamin D status reported for older infants globally based on the latest scientific data. Although we could support the establishment of a mínimum of 1.0 µg/100 kcal. Regards the maximum level our former position was based on the evidence of suboptimal vitamin D status in some regiones, nevetheles is not a health concern in our country, so we could support the maximum level of 3.0 µg/100 kcal.

Recommendation 10

Costa Rica supports the recommended minimun and GUL for B6 vitamin.

Recommendation 11

Costa Rica supports the recommended minimun and GUL for folic acid.

Recommendation 12

Costa Rica supported a minimum level of 1.0 mg /100 kcal because after the age of 4-6 months, body iron stores are dramatically decreased and therefore a supply should be superior to that of IF (CODEX IF). This proposed level is aligned with current CODEX FUF and similar to the ENA FUF guidelines.

Costa Rica supported that the maximun level of iron were determined by national authorities, as it was defined for infant formulae. We already had set a GUL for iron in infant formulae of 2.0 mg /100 kcal, so we consider the same approach could apply for FUF. We still have iron deficiencies in pre school population, and the summary of the discussion mentions the existence of conflicting evidence, so it is unclear why it is preferably to set a máximum level instead of a GUL in this case.

Recommendation 13

Costa Rica did not previously support the establishment of a GUL for calcium. The current FuF Standard does not specify a maximum or GUL amount, but in the interests of progressing we can accept the proposal of the Chair

Phosphorus

Costa Rica would prefer a minimum of 60 mg/100 kcal but can accept minimum proposed by he Chairs of 25mg/100kcal in the interests of progressing. However we do not support the Chairs suggested GUL nor maximum for phosphorous on the basis that the calcium:phosphorous ratio is the more significant aspect for phosphorous.

Recommendation 14

Costa Rica supports the recommended levels for manganese.

Recommendation 15

Costa Rica supports the recommended levels for iodine.

Recommendation 16

Nevertheless we had supported a minimum of 1.0 µg /100 kcal, Costa Rica supports the recommended levels for selenium,

Recommendation 17

Costa Rica supports the recommended levels for cooper.

Recommendation 18

Costa Rica previously supported a GUL of 1.5 µg /100 kcal aligned with the range in infant formulae. But we can accept also a GUL of 1.0 µg /100 kcal

Recommendation 19

Costa Rica supports the recommended levels for the optional addition of choline.

Recommendation 20

Costa Rica supports the recommended levels for the optional addition of myo-inositol.

Recommendation 21

Costa Rica supports the recommendation for L-carnitine.

Recommendation 22

Costa Rica supports the following statements for the optional ingredients section:

3.3.2 Optional Ingredients

3.3.2.1 [In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

3.3.2.2 [When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect OR benefit~~, [taking into account levels in human milk].~~

3.3.2.3 ~~When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.~~ [The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added].

Taurine

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	12	-
mg/100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic Acid20)

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

20) If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6)

contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	150

Myo-inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	40

L-Carnitine

Levels may need to be determined by national authorities.

3.3.2.4 Only L(+) lactic producing cultures may be used.

NOTE: If the Committee considers that DHA should be a mandatory addition to follow-up formula (for olderinfants), then the provisions relating to DHA may need to be moved to point 3.2.2 – Fat, of the Essential Composition and Quality Factors section of the *Standard for Follow-up Formula* (Section 3). It was also suggested by several eWG members, that if DHA is considered a mandatory addition to follow-up formula (for older infants), then a minimum level should be set.

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

Codex requirement - mandatory additions:

Core (mandatory) composition of follow-up formula for young children will include;

- Protein
- Fat – consider the fatty acid profile, including parameters for ALA and LA and maximum limits for trans fatty acids and saturated fatty acids

- Carbohydrate – based on residual energy after fat and protein contribution has been calculated. Consider including a limit for the addition of sugar.
- Iron
- Calcium
- Vitamin A

Codex requirement - voluntary additions:

In addition to those mandatory macronutrient and nutrient provisions list above, other vitamins and minerals listed for addition to follow-up formula for older infants, may be added to follow-up formula for young children on a voluntary basis. The level of addition for these vitamins and minerals shall meet the requirements stipulated for follow-up formula for older infants.

Codex requirement - Optional Ingredients:

Further to the mandatory and voluntary nutrient additions, other ingredients or substances may be added to follow-up formula for young children as per the optional ingredient principles established for follow-up formula for older infants.

National Authority discretion:

In addition to those provisions listed above, national authorities may require further nutrients be mandated for addition to follow-up formula for young children to meet the nutritional needs of their population. These nutrients can be chosen from the essential compositional requirements for follow-up formula for older infants, in which case the level of addition shall meet the requirements stipulated in that Standard.

Costa Rica supports the core (mandatory) composition of follow-up formula for young children with the addition of Zinc. We also consider it is important to avoid possible excessive intake of sodium as reported in the review of the Codex Standard for follow-on formula (CX/NFSDU/ 14/36/7). We believe that the mandatory additions should be harmonized as much as posible, and less nutrients are left for national and regional authority discretion, for trade facilitation and a clear product caracterization.

Costa Rica supports that compositional requirements of FuF for older infants could serve as a basis for the compositional requirements for FuF for younger children, with the necessary adjustments to further adapt it to the different nutritional requirements as the child grows and consumes an increasingly diversified family diet.

GHANA

Appendix 2

2.1 Product Description

2.1.1 Ghana prefers the second (b) definition but suggests modifying text as follows:

Follow-up formula means a food intended to ***contribute to*** the liquid part of the progressively diversified diet of ***older infants*** and young children.

Rationale: The term “complementary feeding” as defined by WHO already captures breastfeeding and other foods which may be liquid and so to define follow-up as **the** liquid part of the diet for older infants is misleading and it can be perceived as displacing or potentially replacing breast milk or breastfeeding. The definition should encompass all categories of children for whom it is intended to be used hence the suggestion to include older infants in definition b).

2.1.2 Ghana proposes the removal of square brackets in first definition to read:

Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

2.2.2 Ghana supports definition of older infants as;

Older infants means persons from the age of 6 months and not more than 12 months of age.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS (for older infants 6-12 months)

3.1.1 Ghana proposes that, the definition in the standard be maintained with the following modification*:*

Follow-up formula *is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for* ***older*** *infants and young children.*

Rationale*:* This definition caters for both animal and plant sources in the preparation of Follow-up Formula.

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

Recommendations 1- 22: Ghana supports all recommendations made in relation to the nutrient composition for Follow-up Formula. We support the adoption of all nutrients aligned to the Codex Standard for infant formula.

Rationale: The nutrient requirements of this age group is not significantly different except for iron which is required in increasing amounts. However, appropriate complementary feeding which is recommended to start at 6 months is intended to supplement the deficient nutrient in breast milk at this age which includes mainly energy and iron. It is therefore not necessary to increase such nutrients in follow-up formula.

With regards to the recommendation related to carbohydrates, the additional statement related to allowing the use of sucrose and fructose should be deleted as there is no clear criteria of who or where the need for such inclusion should come from, given their possible negative impact, especially to infants and its potential as a predisposition factor for non-communicable diseases later in life.

MOROCCO

GENERAL COMMENTS

Issue	
WHA Resolution	At this step of the discussion, it is not part of the terms of reference of the 2015 eWG as agreed at the last CCNFSDU.

SPECIFIC COMMENTS

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

RECOMMENDATION	COMMENTS
Recommendation 1	Morocco supports the recommendation of the eWG Chair.
Recommendation 2	We support the recommendation of the eWG Chair.
Recommendation 3: Minimum and maximum levels for protein	We supports the recommendation of the eWG Chair.
Recommendation 4: Fat	Morroco supports the recommendation of the eWG Chair.
Recommendation 5: Linoleic and alpha-linolenic	We supports the recommendation of the eWG Chair.
Recommendation 6: DHA, ARA and EPA	Morocco supports the recommendation of the eWG Chair.
Recommendation 7: Carbohydrate	We support the recommendation of the eWG Chair.
Recommendation 8: Vitamin a	Morocco does not support the eWG Chair's. recommendation for a maximum vitamin A level that is aligned with the existing Standard on Infant Formula. Morocco suggest the retention of the existing Standard on Follow-up Formula for Vitamin A with a maximum level of 225µg RE/100 kcal.
Recommendation 9: Vitamin D	We support the eWG Chair's recommendation
Recommendation 10: Vitamin B6	We agrees with the proposal by the eWG Chair to support the minimum at 35 µg /100 kcal, the GUL at 175 µg /100 kcal and the deletion of footnote.
Recommendation 11: Folic acid	Morocco supports the recommendation.

Recommendation 12: Iron	We support the chair recommendation.
Recommendation 13: Calcium & Phosphorus	Morocco support the Chair's proposal
Recommendation 14: Manganese (Section 6.4.3)	Morocco supports the recommendation of the eWG Chair.

OTHER SUBSTANCES: CHOLINE, MYO-INOSITOL & L-CARNITINE (Section 6.5)

	COMMENTS
RECOMMENDATIONS 19,20,21: CHOLINE, MYO INOSITO, L CARNITINE	Morocco agrees with the Chair's recommendation on Choline classified as an optional ingredient.
	Morocco agrees with the Chair's recommendation as optional ingredient.
	Morocco agrees with the Chair's recommendation as Carnitine is considered as an optional ingredient.
JUSTIFICATION	
Based on EFSA 2014	

OPTIONAL INGREDIENTS FOR OLDER INFANTS (6-12 MONTHS) (Section 7)

CHAIR PROPOSAL – OPTIONAL INGREDIENTS (Section 3.3.2)	Morocco supports the chair recommendation

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12 – 36 MONTHS) (Section 8)

CHAIR PROPOSAL (Section 8.2)	**COMMENTS**
The composition of follow-up formula for young children (12-36 months) shall be presented as a narrow list of mandatory nutrients with the option of national authorities requiring additional mandatory nutrients based on the nutritional needs of their population.	Morocco position is that there is a need to assess the nutrients that are of concerns in the diet of this age range. The choice of the nutrients that will become mandatory has to be science based.
MANDATORY ADDITIONS (Section 8.2)	Morocco supports the establishment of criteria for the following mandatory nutrients in follow-up formula for young children: ● Protein ● Fat – consider the fatty acid profile, including parameters for ALA and LA and maximum limits for trans fatty acids and saturated fatty acids ● Carbohydrate – based on residual energy after fat and protein contribution has been calculated. Consider including a limit for the addition of sugar. ● Iron ● Calcium ; Phosphorous ● Vitamin A ● Vitamin B_{12} ● Vitamin D ● Vitamin C ● Zinc ● Iodine

	● Folic Acid ● Sodium
JUSTIFICATION	
In Morocco there is lack of data regarding nutrition intakes from 12 to 36 months, unhealthy feedings habits become more frequent and start very soon. Therefore we do recommend to be more specific for follow-up formula for young children	

CHAIR PROPOSAL – VOLUNTARY ADDITIONS (Section 8.2)	**COMMENTS**
	Mandatory nutritional criteria should be defined for nutrients that are scientifically demonstrated as key. For the optional addition then a minimum level should be established in case of addition. Vitamins and Minerals not listed as mandatory must satisfy the criteria for optional ingredients.
JUSTIFICATION	
Having a clear Codex standard with Max and Min level will support Moroccan authorities in the approval process of those products	

CHAIR PROPOSAL – OPTIONAL INGREDIENTS (Section 8.2)	**COMMENTS**
	We supports the eWG Chair's proposals for optional ingredients based on generally accepted scientific data and can, but not need to be present either in breast milk. Optional ingredients used in follow-up formula for older infants based on these principles should be permitted in follow-up formula for young children.

CHAIR PROPOSAL – NATIONAL AUTHORITY DISCRETION (Section 8.2)	**COMMENTS**
	We support the eWG Chair's proposals for national discretion.

NEXT STEPS (Section 9)

REPORT	**COMMENTS**
	Morocco agrees with Chair's proposals.

NEW ZEALAND

DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)

New Zealand supports the proposed new structure and approach for Section 2 of the Codex Follow-up Formula Standard as presented in the Agenda Paper. This proposal aligns with the approach taken in the Codex Infant Formula Standard and would see current definitions 2.2 and 2.4 moved to other sections of the Standard; definition 2.2 moved to Section 3 – Essential Composition, and definition 2.4 moved to Section 9.5 – Information for Use.

With regards to definition 2.1.1, New Zealand supports one definition for follow-up formula which incorporates separate product categories and includes a description of the role and purpose for the two different age ranges (that being older infants 6-12 months and young children >12 – 36 months). The definition should not imply that follow-up formula is the only suitable liquid option for feeding older infants and young children. New Zealand supports the proposal presented in the Agenda Paper to provide a definition for *'older infant'* in Section 2. New Zealand is of the view the inclusion of a definition for *'older infant'* is

important as proposed definition 2.1.1 does not include a qualifier or age range for *'older infant'.* Older Infant is already defined in the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013).

New Zealand would not object to the age ranges being included in the definition (see below):

Follow-up formula means a food intended for use as:

a) ***a*** *liquid part of the diet for older infants (from the age of six months (or 6-12 months)) when complementary feeding is introduced; and*

b) *a liquid part of the [progressively] diversified diet of young children (>12-36 months).*

Regarding the definition of follow-up formula for older infants it is proposed that 'the' is replaced with 'a' to reflect the current wording in the Codex Standard for Follow-up Formula and that follow-up formula is one component of the liquid diet, in addition to breast milk, water, or infant formula.

New Zealand prefer the use of the term progressively but would be satisfied to go with the majority regarding this terminology. We support the replacement of the term 'weaning diet' with 'complementary feeding' as was supported by the eWG.

New Zealand agrees to retain the current definitions for *'infant'* and *'young child',* definitions 2.1.2 and 2.1.3 respectively.

New Zealand supports removal of definition 2.1.4 relating to the term calorie. As an alternative approach for consideration, New Zealand proposes that a conversion factor for kJ to kcal could be included as a footnote to Section 3.1 – Energy Content

With regards to current definition 2.2, New Zealand supports moving this Section3 – Essential Composition. Our preferred wording is as follows:

> ***Follow-up formula*** *is a product based on the milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the intended age range.*

New Zealand agrees with the inclusion of the concept of 'supporting growth and development' and therefore supports the addition of the following statement (in preference to the alternative presented in the Agenda Paper);

> *The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.*

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

In general NZ supports the approach outlined in the Agenda paper whereby the guiding principle for establishing compositional requirements for follow-up formula is to align where possible with the Codex Infant Formula Standard, unless differences are scientifically justified.

Recommendation 1

New Zealand supports Recommendation 1 to agree to revise the essential composition of follow-up formula to the levels per 100 kcal specified in the Codex Standard for Infant Formula for the following nutrients: Energy, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B12, pantothenic acid, vitamin C, biotin, magnesium, sodium, chloride and potassium

Recommendation 2

New Zealand supports amendment of the conversion factors for the essential composition of kcal to kJ using the International Standard Unit conversion factors and conventional rounding, as proposed in the Draft Standard.

Recommendation 3 to 18

New Zealand supports further discussions at the physical working group regarding these nutrients. As stated above, in general NZ supports alignment with the Codex Infant Formula standard where possible, unless differences are scientifically justified. Of those nutrients listed in recommendation 3 to 18, NZ considers that there is strong scientific justification to establish different amounts of iron in follow-up formula compared to infant formula due to differences in nutritional requirements between these two age groups.

OPTIONAL INGREDIENTS FOR OLDER INFANTS (6-12 MONTHS)

New Zealand supports incorporating the optional ingredient provisions within 3.2.3 and 3.2.4 of the Infant Formula Standard in to the Follow-up Formula Standard. The incorporation of these optional ingredient permissions should not be viewed as an exclusive list, or "positive list" (see proposed wording in 3.3.2.3 which New Zealand supports).

Consideration should also be given to whether revised CODEX STAN 156-1987 should also state that if ingredients and substances are scientifically assessed and approved for use in infant formula for more vulnerable infants (0-6 months), these same ingredients and substances do not require separate assessment and approval for use in follow up formula for older infants and young children.

Recommendation 22:

New Zealand supports the approach presented in the Agenda Paper, that being, the inclusion of choline, myo-inositol, and L-carnitine as optional ingredients. We look forward to discussions on the exact levels to be established at the physical working group.

New Zealand also supports the following wording:

3.3.2 **Optional Ingredients**

3.3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.*

3.3.2.2 *When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect.*

3.3.2.3 *The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added.*

Taurine

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	12	-
mg/100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic Acid[20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

[20)] [If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.]

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	[150]

Myo-inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	40

L-Carnitine
Levels may need to be determined by national authorities.

3.3.2.4 Only L(+) lactic producing cultures may be used.

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

As discussed in the Agenda Paper, New Zealand agrees that it would be beneficial to work towards establishing a clear approach for deciding on those nutrients that the Committee considers should be mandatory additions to follow-up formula for young children. After giving consideration to the key themes emerging from the eWG, New Zealand supports the approach proposed by the Chairs in the Agenda Paper, that being; the composition of follow-up formula shall be presented as a narrow list of mandatory nutrients with the option of national authorities requiring additional mandatory nutrients based on the nutritional needs

of their population. New Zealand also considers that careful consideration should be given to enable flexibility within the standard to cover both highly formulated products, and modified or fortified milks. New Zealand acknowledges that the core list of mandatory additions presented by the Chairs (protein, fat, carbohydrate, iron, calcium and vitamin A) may require further exploration, and welcomes robust discussion at the Committee meeting on this.

In addition, New Zealand supports an approach where further to the mandatory additions, other vitamins and minerals may be voluntarily added to follow-up formula for young children, provided these are listed and within the parameters presented for follow-up formula for older infants. Optional ingredient provisions should also be retained as per the principles established for follow-up formula for older infants.

NORWAY

(i) General Comments

Norway is a member of the European Free Trade Organisation (EFTA), and therefore Norway has the same legislation on infant formula and follow-on formula as the EU. As the EU already has explained in their responses to the eWG, this legislation is in the process of being revised and is soon expected to be adopted.

(ii) Specific Comments

General comment to the minimum requirements of nutrients

Several of the proposed minimum requirements for nutrients in CX/NFSDU 15/37/5 deviate from the forthcoming EU legislation on infant formula and follow-on formula in EU, which is based on the recent scientific opinion of EFSA. We have not made specific comments on the minimum levels, except for protein and vitamin D, at this stage.

Section 3.1.3 a) - Protein

a) Protein[2), 3), 4)]			
Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	[1.8]	~~[3.5]~~ [**2.5**]	-

Norway supports a minimum of 1.8 g protein/100 kcal.

Norway is of the opinion that a maximum of 3.5 g protein/100 kcal is too high, and proposes a maximum of 2.5 g/100 kcal.

Rationale:

The protein requirement for older infants is calculated to 10.2 g per day, based on the WHO/FAO/UNU protein requirements (2007) and the WHO Multicenter Growth Study Growth Standards (2006)[1].

With a representative caloric intake of 500 kcal/day, a maximum limit of 2.5 g/100 kcal corresponds to 12.5 g protein per day, which exceeds the requirement of 10.2 g per day. In addition to this, complementary feeding would also provide some protein.

Several nationally and regionally representative surveys of dietary protein intakes of older infants and young children have been conducted globally, and the results of these surveys have consistently identified that protein intakes in this age group are adequate for the majority of infants and young children, and may even be excessive. In addition some studies suggest that excessive protein intake in early childhood may associated with differences in growth and obesity risk late in life. Even though there is no conclusive evidence of this, we are of the opinion that this implies a lower max limit for protein, in order to avoid potential risks associated with high protein intakes.

In summary, there is no need to exceed a maximum limit of 2.5 g/100 kcal, and high protein intakes should be avoided in order to reduce possible associated risks.

[1] Report of the eWG FUF 2014 (CX/NFSDU 14/36/7)

Section 3.1.3 d) - Vitamins

Vitamin A			
Unit	**Minimum**	**Maximum**	**GUL**
µg RE[10)]/100 kcal	[75]	~~[180]~~ [**114**]	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration

of vitamin A activity.

Norway is of the opinion that a maximum of 180 µg RE/100 kcal is too high, and proposes a maximum of 114 µg RE/100 kcal, which is the current proposed maximum level in the forthcoming EU legislation on infant formula and follow-on formula.

Rationale:

According to EFSA (2014), children are particularly sensitive to vitamin A. The Scientific Committee of Food (SCF) has recommended an Upper Tolerable Intake level (UL) of 800 µg RE/day for 1-3 years old children[1], and WHO/FAO has established an UL of 600 µg retinol[2].

Assuming an intake of 500 kcal per day from follow-on formula and a maximum limit of 180 µg RE/100 kcal, the intake of vitamin A from follow-on-formula alone would add up to 900 µg/day, exceeding the suggested upper limit of both 600 µg RE/day (WHO) and 800 µg RE/day (SCF), even without considering extra vitamin A from complementary food, which may be considerable.

The maximum limit of 180 µg/RE/100 kcal thus seems to be too high and we suggest that it is lowered.

A maximum limit of 114 µg RE/100 kcal will equal to 570 µg RE/day when assuming a caloric intake of 500 kcal/day. This is well above the intake level considered adequate for the majority of infants (400 µg RE/day for the 6-36 month age group (WHO 2004); 350 µg RE/day for the 6-12 month age group (EFSA 2013)). This level also allows for some vitamin A intake from other foods in a progressively diversified diet, without exceeding the UL.

[1] Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retinyl esters). 7 October 2002.

[2] WHO. A model for establishing upper levels of intake for nutrients and related substances: Report of a joint FAO/WHO technical workshop on nutrient risk assessment. 2006

Vitamin D

Unit	**Minimum**	**Maximum**	**GUL**
µg[11)] /100 kcal	~~[1.0]~~ [**2.0**]	[3.0]	-

[11)] Calciferol. 1 µg calciferol = 40 IU vitamin D.

Norway supports a maximum of 3.0 g vitamin D/100 kcal.

Norway is of the opinion that a minimum of 1.0 g vitamin D/100 kcal is too low, and proposes to elevate the minimum requirement of vitamin D to 2.0 g/100 kcal.

Rationale:

Reviews of vitamin D requirements that have recently been conducted recommend elevating the DIRV for infants and young children. An intake of at least 10 µg is considered adequate for the majority of older infants and young children with minimal exposure to sun (IOM 2011 and NNR 2012), and this DIRV was proposed by the eWG of 2014[1].

Vitamin D insufficiency is generally limited to populations or sub-groups of the population with limited sunlight exposure and where no public health interventions have been implemented. Vitamin D insufficiency has also been observed in some lower latitude countries (Mexico, Indonesia, Malaysia, Thailand, Iran and Jordan)[1].

EFSA (2014) has proposed a minimum content of vitamin D in follow-on-formula of 2 µg/100 kcal. This level is based on the intake levels of vitamin D considered adequate for this age group of 10 µg/day based on 25(OH)D vitamin serum concentrations, and assuming an average energy intake of an infant below six months of age of 500 kcal/day.

[1] Report of the eWG FUF 2014 (CX/NFSDU 14/36/7)

Vitamin B_{12}

Unit	**Minimum**	**Maximum**	**GUL**
µg /100 kcal	0.1	-	~~1.5~~ [**0.5**]

Norway suggests lowering GUL to 0.5 µg/100 kcal, which is in accordance with the current proposed maximum level in the forthcoming EU regulation.

Rationale:

A vitamin B12 intake of 0.5 µg/day is considered adequate for the majority of older infants (IOM 1998, NHMRC/MoH 2004, NNR 2012, EFSA 2013), and this and this DIRV was proposed by the eWG of 2014.

Assuming a caloric intake of 500 kcal per day, a maximum content of 1.5 µg/100 kcal in follow-up formula results in a daily intake of 7.5 µg vitamin B 12. This is 15 times higher than the requirement, and seems unnecessary high. A maximum content of 0.5 µg/100 kcal corresponds to 2.5 µg vitamin B 12/day (i.e. 5X DIRV), which seems more reasonable.

Section 3.1.3 e) Minerals and Trace Elements

Iron[17]			
Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	~~[1.0]~~ [**0.6**]	[2.0]	-

[17] For Follow-up formula based on soy protein isolate a minimum value of 1.5/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6/100 kJ) applies]

Norway supports a maximum of 2.0 g iron/100 kcal.

Norway suggests that the minimum requirement in follow-up formula is lowered from 1.0 to 0.6 mg/100 kcal, in accordance with EFSA and the current proposed minimum level in the forthcoming EU regulation.

Rationale:

According to EFSA, studies suggest that iron replete infants might be at risk of negative health consequences, including impaired growth and development and an increased risk of infections, if given extra iron. The existing evidence suggest that the absorption of iron cannot be down-regulated before the age of nine months, with a risk of overload in those infants with sufficient iron stores but high iron intakes. The iron content of infant formula and follow-up formula should thus not be unnecessary high.

An international expert group in 2013 recommended a level of 1.1 to 1.9 mg/100 kcal[2]. However, an ESPGHAN expert group in a position statement from 2014[3] concludes that "Follow-on formulas should be iron fortified; however, there is not enough evidence to determine the optimal iron concentration in follow-on formula", taking into account (2). Based on this, Norway suggests that the EFSA lower limit of 0.6 mg/100 kcal is chosen.

EFSA[1] considers that it is reasonable to assume that a daily intake of 8 mg iron per day may be reached with an intake of 600 mL follow-up formula with an iron content of 0.6 mg/100 kcal and intake of complementary foods containing 5.7 mg per day (70% of the recommended iron intake).

[1] EFSA. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014; 12(7):3760.)

[2] Koletzko B, Bhutta ZA, Cai W et al. Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordianted by the early nutrtion acedemy. Ann Nutr Metab 2013;62:44-54.

[3] Domellöf M, Braegger C, Campoy, C. et al. Iron requirements of infants and toddlers. JPGN 2014; 58: Nr. 1.

Iodine			
Unit	**Minimum**	**Maximum**	**GUL**
µg /100 kcal	[10]	[**29**]	~~[60]~~

Norway is of the opinion that a GUL of 60 µg iodine/100 kcal is too high, and proposes a maximum of 29 µg iodine/100 kcal, which is the current proposed maximum level in the forthcoming EU regulation on infant formula and follow-on formula in EU.

Rationale:

The Scientific Committee of Food (SCF) has recommended an Upper Tolerable Intake level (UL) of 200 µg iodine/day for 1-3 years old children[1]. Assuming an intake of 500 kcal per day from follow-on formula and a maximum limit of 60 µg iodine/100 kcal, the intake of iodine from follow-on-formula alone would add up to 300 µg/day, exceeding the UL.

The proposed GUL of 60 µg iodine/100 kcal thus seems to be too high and we suggest that it is lowered.

A maximum limit of 29 µg iodine/100 kcal will equal to 145 µg iodine/day when assuming a caloric intake of 500 kcal/day. This is well above the intake level considered adequate for the majority of infants of 90 µg iodine/day for the 6-36 month age group (WHO 2004) (proposed by the eWG of 2014). This level also allows for some iodine intake from other foods in a progressively diversified diet, without exceeding the UL.

[1] Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine. 26 September 2002.

Zinc[20)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	[**1.0**]	~~[1.0]~~

[20)] For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) and maximum of 1.25 mg/100 kcal (0.3/100 kJ) applies

Norway supports a maximum of 1.0 mg zinc/100 kcal, which is the current proposed level in the forthcoming EU regulation on infant formula and follow-on formula in EU.

Rationale:

The Scientific Committee of Food has recommended an Upper Tolerable Intake level (UL) of 7 mg zinc /day for 1-3 years old children[1], and IOM[2] has set an UL of zinc for infants 7-12 months of 5 mg/day. Assuming an intake of 500 kcal per day from follow-on formula, and a maximum limit of 1 mg zinc/100 kcal, the intake of iodine from follow-on-formula alone would add up to the UL set by IOM. Therefore, the level of 1 mg zinc/100 kcal should not be established as GUL, but a maximum limit.

[1] Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Zinc. 5 March 2002.

[2] Institute of Medicine 2001. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, etc.

Section 3.3.2 Optional ingredients

~~3.3.2.4 Only L(+) lactic producing cultures may be used.~~

Norway proposes to delete section 3.3.2.4.

Rationale:

Several risk evaluations from the Norwegian Committee for Food Safety of lactic acid producing cultures in products to infants[1,2] showed that they did not fulfill the requirements to safety and suitability for the specific group they were intended for. It was concluded that a daily support of a monoculture of a particular strain in large quantities, and to an age group without a fully established intestinal flora, may have unknown adverse effects.

Based on these risk evaluations, Norway is of the opinion that microbiological cultures should not be added to follow-up formula.

As opposed to this, section 3.3.2.4. indicates that it is safe to add L(+) lactic producing cultures to follow-up formula. Norway therefore proposes to delete section 3.3.2.4.

[1] Assessment of infant formula and follow-on formula supplemented with Lactobacillus fermentum CECT5716. Opinion of the Norwegian Scientific Committee for Food Safety 2014.

2 Risk assessment on use of Lactobacillus rhamnosus (LGG) as an ingredient in infant formula and baby foods (II). Opinion of the Norwegian Scientific Committee for Food Safety 2007.

PHILIPPINES

The Philippines expresses its appreciation to the electronic working group chaired by New Zealand and co-chaired by France and Indonesia for its work in the Draft Revision to the Standard for Follow Up Formula.

The Philippines supports the Proposed Draft Revision to the Standard for Follow Up Formula with minor modifications. These comments are aligned with the Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants and consistent with the previous Philippine positions as responses to a series of consultation papers of this electronic working group based on current scientific evidence. We agree with the proposed levels of vitamins and minerals as outlined in the draft.

2**. Description**

2.1 **Product Definition**

We support the proposed statement in Section 2.1.1 since the definition of follow up formula includes the introduction of complementary foods for older infants and specifies that follow up formula is intended to be a part of the diversified diet of young children. It is deemed appropriate to mention introduction of complementary foods in the definition of follow up formula since such foods are part and parcel of the diets of older infants. It is consistent with the WHO Global Strategy for Infant and Young Child Feeding (WHO/UNICEF 2003).

Aligning Section 2 with Infant Formula standard will provide consistency between both standards in terms of definitions, terminology and structure.

2.1.1 Follow up Formula means a food intended for:

(a) the liquid part of the diet for older infants when complementary feeding is introduced; and

(b) a liquid part of of the progressively diversified diet of young children

2.1.2 The Philippines proposes to retain the second bracketed statement [[Follow up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage, distribution in the country where the product is sold]. This statement is consistent with the Codex Standard for Infant Formula and Formula for Foods for Special Medical Purposes for Infants. We prefer a more individualized approach in dealing with the safety of the product, specifically considering the country where it is sold. We agree with the chair's proposal on one definition that separates the two product categories: older infants in one hand and young children in the other hand. This allows to clarify the separate product categories with their respective role and purpose in the diet.

2. 2 **Other Definitions**

2.2.2 We support retaining the bracketed statement defining the older infants [Older infant means persons from the age of 6 months and not more than 12 months of age.] since its use is relevant and useful in the entire document. It is consistent with the definition of the Codex Guidelines for Formulated Complementary Foods for Older Infants and Young Children.

Essential Composition and Quality Factors (for older infants 6-12 months)

3.1.1 We prefer the following statement to be under Essential Composition: Follow up formula is a product based on milk or milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable and nutritionally adequate to support growth and development for older infants and young children. We believe that this statement elaborates the basic composition of follow up formula and provides a clearer description of the ideal quality of follow up formula compared with the rest of the bracketed statements. We agree with the inclusion of the concept of "supporting growth and development. This is aligned with the Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants.

We also agree with the retention of the bracketed statement [The nutritional safety and adequacy of follow up formula shall be scientifically demonstrated to support growth and development of older infants and young children.] This is aligned with the Infant Formula Standard in reference to safety and adequacy. It denotes the continuity of research that should be done in ensuring that the product meets the current need for growth and development of the targeted population.

3.1.3 **Protein**

We are of the opinion that the minimum value of 1.65g/100kcal should be considered as 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). Randomized clinical trials confirmed the safety and suitability of a formula with a protein content of 1.65g/100kcal. It was observed that growth of infants fed a high quality protein formula at 1.61g protein level/100kcal in later infancy was similar to the growth of infants fed with control formula and closer to breastfed infants (Ziegler 2015; Inostroza 2014). The set protein level (ENA, 2013) considered several criteria in the context of: population reference intakes for dietary protein intake per day calculated to meet the needs of basically all infants in the population with an adequate safety margin; complementary feeding and family foods provide 10-15% of energy as protein; protein intakes are generally far above requirements. In addition, reducing the protein content of formula for infants may effectively contribute to the prevention of childhood obesity (.

We recommend to retain the bracketed texts [and goats'] and [2.25 g/100 kcal (0.5 g/100 kJ] in these statements: The minimum value applied to cow's and goats' milk protein, for follow-up formula based on non-cow's milk protein other minimum values may need to be applied. For follow-up formula based on non-cow's milk protein, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies. Setting the minimum value for protein is imperative since high protein intakes during the first year of life were shown to lead to excessive weight gain which can increase the risk of obesity and associated diseases (Koletzko, 2013). It is important to specify goat's milk protein to emphasize other sources of protein. It is also apppropriate to set the minimum value of protein for follow up formula based on soy protein isolate to ensure its suitability for growth and development of older infants and young children.

Recommendations for protein levels of protein hydrolysate containing formulas should be properly reviewed by the EWG since Expert Authorities expressed the need to validate the nutritional suitability of hydrolysed

protein formulas at 1.8g/100 cal level, which is above the minimum established for intact protein formulas. However, hydrolysed protein should continue to be used in follow-up formulas as suitable protein for older infants.

Zinc

We support to maintain a minimum proposed level for zinc of 0.5mg/100kcal. The proposed reduced zinc range of 0.5mg (0.5-1.0 mg/100kcal) (compared to the existing Codex Infant Formula Standard for Zinc range of 1mg (0.5-1.5 mg/100kcal) may be an issue from manufacturing point of view as too narrow due to variability (raw materials, process, etc.) and would limit zinc fortification, which is not desirable. Indeed, zinc deficiency is still an important cause of morbidity in developing countries and is reported to account for 1.7% of deaths in children less than five years of age (Black 2013). In the recent EFSA report on dietary intakes and status of older infants and young children, almost all national surveys have observed that between 21 and 56% of older infants and young children were zinc deficient (EFSA 2013). This has also been observed in low income countries like Cameroon or Uganda (CX/NFSDU 14/36/7). For these reasons, we support to align with zinc recommendations in the Codex Infant Formula Standard and Koletzko et al (2013) and set a GUL at 1.5mg/100kcal.

Vitamin B6

We do not support to maintain the footnote ("Formulas should contain a minimum of 15 mcg vitamin B6 per gramme of protein"). There is no universal consensus on this point. It is neither specified in the Infant Formula Standard nor in EFSA recommendations. Additionally, the proposed protein levels being lower (possibly up to min. 1.65g/100kcal) than those found in the current FUF standard (3.0g/100 kcal), the minimum Vitamin B6 content established based on this footnote would be consequently lower (24.8 mcg /100 kcal). As we would like to support the minimum level of 35 mcg/100kcal, together with the lower protein level, this footnote would not be compatible with this proposal.

3.3.2 Optional Ingredients

3.3.2.2 We support the 2nd bracketed statement to wit "In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow up formula for older infants where safety and suitability of the optional ingredients, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence." It is critical to set qualifying factors relative to the use of other ingredients or substances for follow up formula taking into account safety, suitability, amount of use and demonstration of scientific evidence since these should be paramount considerations in the selection of optional ingredients for this product.

3.3.2.2 The Philippines supports retaining this bracketed statement" [When any of these ingredients or substances is added, the formula shall contain sufficient amounts to achieve the intended benefit taking into account levels in human milk.] The amount of optional ingredients should be adequate for the intended effect considering levels found in breastmilk since human milk is an ideal part of the progressively diversified diet up to two years of age and beyond. The levels of ingredients should mimic the levels found in breastmilk in order to support the older infant's physiological requirement for a particular optional ingredient. For instance, the study of Singhal et al (2008) supports the hypothesis that nucleotide supplementation of formula to a higher concentration, more similar to the total available to breastfed infants, is required for a protective effect against diarrhea.

3.3.2.3 It is important to retain this bracketed statement [The following substances maybe added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added]. The first statement is important since it emphasizes levels of other ingredients in compliance with national law with levels within those specified in the list. The second statement is also critical indicating that the listed levels are guide levels for national regulators in case such optional ingredient is added.

We support the statament that national authorities may require other nutrients be mandated for addition to follow-up formula for young children in order to meet the nutritional requirements of the young children population. These nutrients can be selected from the essential compositional requirements for follow-up formula for older infants, where addition of nutrient levels shall meet the requirements stipulated in the set Standard.

Option for consideration

We suggest to add vitamin D, Zinc, and Iodine as mandatory nutrients in addition to the nutrients listed under section 8.2 (protein, fat, ALA, LA, CarbohydratES, iron, calcium and vitamin A. These nutrients are frequently found to be limited in the diets of young children, even if these differed regionally as acknowledged by CCNFSDU.

Energy should also be listed in the list of mandatory criteria for two reasons.

- Correct nutrient density of products is key to avoid under and over- energy supply.
- The Chairs propose that carbohydrate content is "based on residual energy after fat and protein contribution". Therefore energy density must be defined.

We are of the opinion that the composition of follow up formula for young children should provide adequate supply of nutrients in the context of the overall diet, particularly for some nutrients like proteins, fats (if full fat milk ± addition of vegetable oils), energy, potassium.

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UNITED STATES OF AMERICA

General Comments

The United States considers that the bracketed proposed definition in 2.1.1 [***Follow-up formula*** *means a food intended for use as (a) the liquid part of the diet for older infants when complementary feeding is introduced; and (b) the liquid part of the progressively diversified diet of young children]* contains a conceptual framework and point of differentiation at 12 months as described under ToR 2. , and we would support removing the brackets from this definition.

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

The United States would support the use of the nutrient standards provided in the Infant Formula Standard (CODEX STAN 72 – 1981), as the standard for FUFs intended for older infants (6-12 months). The eWG Chairs' recommendations to use the Infant Formula Standard could be the starting point for determining the essential composition of FUF for the older infant and adjusting minimum, maximum, or guidance upper levels as appropriate, based on scientific evidence. The United States notes the agreement for such an approach by many members of the eWG. We consider it also important that when DHA is added, ARA should also be added at scientifically based levels and appropriate ratios.

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

The United States supports consideration of the key themes of the eWG on the approach for determining the composition of FUF for young children.

AFRICAN UNION

DESCRIPTION

Issue: 2.1.1 Follow-up formula means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.]

Position: AU proposes the following change to the definition that *'Follow-up formula means an optional food intended for use by older infants when complementary food is introduced and by young children'*

Rationale: Follow-up formula is not a mandatory part of complementary feeding as advised by WHO. It is usually presented in powder form and not necessarily as a liquid. Further, the proposed definition may mislead both the consumers and regulators to believe that follow-up formula is an essential part of complementary feeding contrary to the infant and young child feeding strategies in most countries.

Issue: 2.1.2 **[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold].

OR

[Follow-up formula is so processed ~~by physical means only~~ and ~~so~~ packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] ~~and~~ distribution [and sale] ~~in the country where the product is sold~~].

Position: AU supports the adoption of option 1

Rationale: Food processing may either be physical or chemical and/or a combination of the two. Given the vulnerability of the target group especially the infants, chemical processing should totally be discouraged consistent with the standard for infant formula.

Issue: 2.2 **Other Definitions**

Position: AU supports the adoption of the definitions under clause 2.2 as proposed

Rationale: The definitions are consistent with other Codex texts

Issue: Recommendations 1 – 22 Nutrient composition for follow-up formula for the age 6 – 12 months

Position: Consistent with our previous position, and as proposed by the eWG AU supports the adoption of all nutrients aligned to the Codex Standard for infant formula and where there is deviation such as in Iron, the levels provided in infant formula should be adopted.

Rationale: The nutritional requirements at the age between 6 – 12 months compared to 0 – 6 months is not significantly different except for iron whose need increases during this age. However, appropriate complementary feeding which is recommended to start at 6 months is intended to supplement the deficient nutrient in breast milk at this age which includes mainly energy and iron. It is therefore not necessary to increase such nutrients in follow-up formula. The primary aim should be to ensure safety and quality of the products consistent with the justification for its revision. In regard to the recommendation related to carbohydrates, the additional statement related to allowing the use of sucrose and fructose should be deleted as there is no clear criteria of who or where the need for such inclusion should come from given the negative impact of the nutrients especially to the infants and non-communicable diseases later in life.

Issue: 3.3.2 Optional ingredients

3.3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added ~~when required~~ to ~~ensure that~~ the product [provided the product] is [**safe and**] suitable to form part of a [**progressively diversified diet**] OR [**the complementary diet**] intended for use [**from 6th months on**] OR [**from the age of 6 months/from 6 months of age**] OR [**by older infants**].*

OR *[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]*

Position: AU supports the adoption of option 2

Rationale: The statement is consistent with our proposed definition and that it recognized that the standard is revised based on safety and quality not on nutritional basis.

3.3.2.2 ~~The usefulness of these nutrients shall be scientifically shown.~~ *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~, taking into account levels in human milk~~.]*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit, ~~[taking into account levels in human milk].]~~*
Position: AU supports the adoption of second option deleting the bracketed part

Rationale: The product is produced to have a specific impact/effect and that it should not be compared to breast milk. This comparison has the effect of negatively affecting breast feeding as it will try to allude that the product is same as breast milk.

Issue ~~When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.~~ [*The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added].*

Position: AU supports the adoption as amended.

ELC – Federation of European Specialty Food Ingredients Industries

(i) General comments

As a general and preliminary comment, we would like to underline the importance of providing the right nutrients for those children not breastfed. Breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants. Therefore, breastmilk is the benchmark when setting the composition of Follow Up Formula, even when taking into account key nutrients provided by a progressively diversified diet. Quality and diversity of complementary foods varies depending on countries, local cultures, and accessibility of particular foods. For example, long-chain poly-unsaturated fatty acids such as DHA are mainly provided through fatty fish which is not always widely accessible.

For some nutrients, as underlined by the chair and vice-chairs, the composition set in the Infant Formula standard is also valid for older infants. For others nutrients, nutritional needs may be different and therefore an adapted composition is necessary. In order to define which nutrients are key and therefore essential for optimal growth of older infants, scientific evidence is needed. We firmly believe that not only convincing evidence should be taken into account but also probable evidence should be assessed case-by-case in the light of the precautionary principle. The fatty acids DHA and ARA are considered by FAO as conditionally essential for early development as well as for life-long health (FAO report 91 Fats and fatty acids in human nutrition: Report of an expert consultation). Therefore, the precautionary principle should be applied, and DHA and ARA should be part of the essential composition of follow-up-formula for older infants.

(ii) Specific comments

We support recommendations 1, 2 and 5 and have specific comments in relation to recommendations 6 on DHA, ARA and EPA, recommendation 8 on vitamin A, recommendation 9 on vitamin D, and recommendation 22 on optional ingredients.

Recommendation 6

As already expressed in our previous comments, we firmly believe that DHA and ARA should be mandatory and added together due to their critical role in infants' healthy growth and development. The level of intake and the most common complementary foods do not provide sufficient quantities of DHA and ARA in most developing countries. In addition, both pathways are competing for the same enzymes and therefore it's of paramount importance to add both fatty acids in follow-up formula in a balanced manner.

However, we understand the position taken by the chairs of the e-WG who need to find a consensus and therefore appreciate the recommendation 6 for optional addition. If recommendation 6 is accepted, we believe it's important to include a recommendation with regards to the ratio between DHA and ARA or set a range of values for both. We support the inclusion of the footnote from the Infant Formula Standard as indicated in our comments to Recommendation 22.

In case DHA is mandatory, we support the setting of a minimum. Our proposal would be to set a minimum at 0.2% of fatty acids which is in line with a majority of current levels

We would like to underline that the addition of EPA is not favoured in infant nutrition. In particular, EPA directly counters ARA and is thought to be responsible for observations of growth faltering in infants fed DHA-alone formulas. Therefore, in infant nutrition, EPA content should not be too high. This is the reason

behind the footnote in the Infant Nutrition Standard which limits the EPA content to the one of DHA. Furthermore, this is linked to the fact that some Omega3 sources such as fish oils contain both DHA and EPA. Other sources such as algal oils are mainly composed of DHA. We therefore believe that the reference to EPA should be deleted from recommendation 6.

VITAMINS AND MINERALS

Recommendation 8

While we support to retain the minimum vitamin A level, we disagree with aligning the maximum level with the Standard on Infant formula. Vitamin A is highly important to combat infection and blindness. The current maximum level of vitamin A (225 µg RE/100 kcal and 54 µg/100 kJ) has shown a history of safe use and should be retained.

Recommendation 9

Vitamin D is key for the development of bones and also important in a high number of metabolic pathways. The recent EFSA opinion has raised the value to 2 µg/100 kcal, and we firmly believe this is supported by the large body of evidence indicating benefits of higher intakes than previously recommended. In addition, the prevalence of inadequate intake is high even in countries with a lot of sun.

We are in favour of a higher maximum value in order to let sufficient freedom to adapt the vitamin D level to the country specificity. In its 2012 opinion, EFSA set a Tolerable Upper Safe Level at 25 µg/d for infants from 0 to 1. Setting a maximum value at 4.5 µg/100 kcal thus allows to remain below this value for a daily consumption of 500 kcal.

Recommendation 22

We have comments on 2 separate parts on the recommendation 22, namely wording under 3.3.2.2 and Docosahexaenoic Acid (and the DHA related note).

Wording under 3.3.2.2.

We would like to underline our general support of the reference to human milk in the principle for addition of optional ingredients. As indicated in our general comments, breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants. Therefore, breastmilk is the benchmark for key nutrients. We don't have a strong preference for the wording used for paragraph 3.3.2.2. except the fact that we strongly support the reference to human milk be retained.

Therefore we favour the following wording:

3.3.2.2 *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~,~~ **taking into account levels in human milk, as appropriate based on age and the desired contribution of human milk to the diet**.*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit, **taking into account levels in human milk.***

Docosahexaenoic Acid

As expressed in our general comments as well as in our comments to Recommendation 6, we support mandatory addition of DHA and ARA. However, if DHA should remain optional, we agree with the GUL proposed for DHA and the footnote linking the use of DHA to ARA. The additional sentence on EPA is also needed in order to limit the intake of EPA as explained above in our comments to recommendation 6.

DHA related note in case DHA is mandatory

In case DHA is mandatory, we support the setting of a minimum. Our proposal would be to set a minimum at 0.2% of fatty acids which is in line with a majority of current levels.

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

Older infants and young children represent vulnerable groups with specific needs for food safety and quality with a continuum in the nutritional needs of older infants and young children. We agree that a number of nutrients can be found in the diet which increases in diversity between 12 and 36 months. However, a number of studies around the globe indicate, as shown in the last consultation paper, that some nutrients are frequently limited in the diet of older infants and young children. DHA is amongst those nutrients which are not sufficiently consumed.

Limited intake of DHA has been acknowledged by a number of delegations. Given the crucial role of DHA not only during early development but throughout life, we believe it should be part of the essential composition of

follow-up formula for young children.

We would like to stress that newly available data (Exponent data) suggests that not only intakes of DHA are low but intakes of ARA may also be inadequate. Thus a provision of DHA and ARA may be beneficial in providing a valuable safety net, protecting the nutritional status of those young children with inadequate intakes of these key fatty acids.

We support the concept of flexibility in the composition for vitamins and minerals which are essential nutrients but which do not necessarily lack in each part of the world. We also support the proposal to align this composition with the levels of follow-up-formula for older infants.

The proposal to add optional ingredients on the basis of safety and scientific evidence allows for additional adaptation to the nutritional and physiological needs of young children. This concept is in line with EU requirements for safety, suitability and expected benefits. We welcome this element of the proposal.

We also support the additional provision foreseeing national Authority discretion as some nutrients may be considered mandatory in some countries based on culture and dietary practices.

ELC – Additional Comments

ELC is concerned that the proposed use of 5.71 as the nitrogen to protein conversion factor for soy instead of the widely accepted 6.25 factor represents a departure from current Codex Standards, the guidance of globally recognized scientific organizations, member country government regulations, and published scientific literature. This change would also have a significant negative impact on the perception of soy as a nutritious and high-quality protein, and we therefore kindly request:

1. The deletion of the third sentence in Footnote #2 of CODEX STAN 156-1987 as follows:

   Footnote 2

   2For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. ~~The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.~~

2. The assessment of the appropriate nitrogen to protein conversion factor for soy to be referred to the Codex Committee for Methods of Analysis and Sampling (CCMAS). Nitrogen to protein conversion factors represents an analytical matter and we believe they should be referred to the appropriate Codex Committee with expertise in this matter. This would be consistent with the mandate the CCMAS received on this issue from the 38th CAC.

In support of our two requests stated above, we provide the following:

What is the origin of 6.25 ?

The Kjeldahl method, the modified Kjeldahl method, and the combustion method (known as the Dumas method) are commonly used for analytical measurement of protein. These methods measure protein in foods indirectly by assessing the quantity of nitrogen that can be released from a protein and captured as ammonia. Nitrogen from all nitrogenous compounds, including proteins and non-protein material, are typically included in this total. In the early 1880s, when the Kjeldahl method was invented, proteins readily available for testing (serum albumin and globulin from blood, casein from milk) contained about 16% nitrogen. Dividing 100 by 16% gave a nitrogen conversion factor of 6.25 and it was believed that this factor applied to all proteins. Although it has since been discovered through further scientific research that few foods contain precisely 16% nitrogen, use of the 6.25 conversion factor for measurement of protein sources has been maintained to allow for a measure of international harmonization in the expression of protein levels.

What is the origin of 5.71?

In 1931 (revised in 1941), USDA scientist D.B. Jones published a report ("Circular 183")[1] which proposed establishing unique nitrogen to protein conversion factors for several foods. Jones reported 5.71 as a more "precise" factor for soy protein. In this Circular[1], Jones hypothesized that not all nitrogen in foodstuffs was protein nitrogen and not all proteins contained 16% nitrogen; therefore, a universal conversion factor of 6.25 was not always appropriate. In support of his theory, Jones reported nitrogen contents for several plant and animal proteins from a variety of sources. Jones justified the 5.71 factor for soybeans by stating, **incorrectly**, that the major protein in soybeans is glycinin, a globulin composed of 17.5% nitrogen. From these data, he designated a conversion factor for soy protein of 5.71 (100 divided by 17.5 results in a factor of 5.71).

Glycinin (11S), however, represents only about 31-52% of the total protein in soybeans[2-4]. There are many other proteins in soybeans, including beta-conglycinin (7S), which represents about 35% of the total protein[2-

[4]. **If one considered only the 7S protein, the nitrogen to protein conversion factor for soy would be as high as 6.45**[3,4]. The ratios of 11S to 7S in soybeans will vary significantly, depending on the soybean variety and differences in seasonal growing conditions[2-4].

What is the Support for 6.25

The 6.25 nitrogen conversion factor is recognized by Codex Alimentarius as the appropriate conversion factor for determining the protein content of a soy product per the following Codex Standards:

- Codex Standard 175-1989 Codex General Standard for Soy Protein Products[5]
- Codex CAC/GL 2-1985 Guidelines on Nutrition Labelling (as amended by the 29th Session of the Commission, 2006)[6]
- Codex Standard 234-1999 Recommended Methods of Analysis and Sampling (as amended by the 30th Session of the Commission, 2007)[7]

Although an exhaustive list of regulations from around the globe was not assessed, the nutrition labeling regulations or regulatory product composition standards for the following countries representing a significant portion of the world's population list 6.25 as the N conversion factor for soy protein:

- Select National and Regional Government Nutrition Labeling Regulations
  - Argentina[8]
  - Brazil[9]
  - China[10] (for soy protein ingredients, isolated soy protein & soy protein concentrate)
  - European Union[11]
  - India[12]
  - Japan[13]
  - Korea[14]
  - Malaysia[15]
  - Mexico[16]
  - South Africa[17]
  - United States[18]

The following globally recognized analytical sciences associations identify 6.25 as an appropriate nitrogen conversion factor for soy in their current official analytical methods:

- American Oil Chemists Society (AOCS)[19-22]
- AOAC[23]
- AACC International (AACC)[24-27]
- International Organization for Standardization (ISO)[28]

Soy is a Source of High-Quality Protein

In addition, soy is a source of high quality plant protein, comparable to meat, milk, and eggs. Numerous nitrogen balance studies found soy protein is comparable to milk and meat in its ability to support N balance[29-34]. The 6.25 nitrogen to protein conversion factor was used by researchers to calculate gram amount for **both** soy and animal-based protein fed to study subjects. Rand, et al., 2003[35] conducted a meta-analysis of nitrogen balance studies that was used to estimate protein requirements for healthy adults and found soy protein is comparable to milk and meat in its ability to support nitrogen balance. Rand et al. stated, "These original soy studies showed clearly that the well-processed soy proteins were equivalent to animal protein, whereas wheat proteins were used with lower efficiency than were animal protein (beef)"[35].

The Protein Digestibility-Corrected Amino Acid Score (PDCAAS) is the currently accepted and validated method for protein quality measurement based on the principle that the nutritive value of a protein depends on its ability to provide amino acids in adequate amounts to meet the requirements of children and adults[36]. The PDCAAS for isolated soy protein and soy protein concentrate is equal to 1.0, comparable to milk and egg proteins[37, 38].

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ENSA – European Natural Soyfood Manufacturers Association

General comments

By the age of 12 months (start age for group of young children), milk consumption is reduced as a proportion of dietary intake, **as toddlers begin to take part in family meals and need various types of food products to satisfy their growing nutritional needs**.

The young child products marketed by ENSA members are 100% plant-based and are made **from the whole soybean, using a natural process**: soybeans are soaked in water, milled and other ingredients and components may be added e.g. vitamins and minerals. The drinks contain the natural nutrients of the soybean, such as high quality soy protein and mainly unsaturated fats, including the 2 essential fatty acids, linoleic acid and alpha-linolenic acid.

These soy foods for young children (12 to 36 months) are **totally different from the Follow-up-Formula (FUF) for older infants (6 to 12 months) as well as from young child formula made on the basis of isolated soy protein (ISP).**

The whole soybean drinks represent today a small percentage of the market for young children but their market share is growing and they fulfill **a clear need for the consumer**: mothers who do not want to continue the use of infant and FUF formula but want their children (12 to 36 months old) to consume drinks made from the whole soybean, because of cow's milk protein allergy or just because they prefer plant-based products in the diet.

As such **whole soybean drinks, which are plant-based alternatives to milk, should be included in the standardfor follow-up formula for young children**. Although we acknowledge that certain nutrients may have to be added to the FUF for young children to accommodate the specific needs of this age group, **we support** the findings that follow-up formula for young children does not need to be as prescriptive as follow-up formula for older infants.

Specific comments

5. Description of follow-up formula (section 2)

In regards to the proposed changes to the current definition 2.2:

Follow-up formula *is a [food] OR [product] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,~~ [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. ~~infants from the 6th month on and for young children.~~*

In the definition all reference to plant-based products have been deleted while there is, based on the general comments mentioned above, a clear need for including plant-based products, such as whole soybean drinks in this definition.

Therefore the following changes are proposed:

> *Follow-up formula is a [food] OR [product] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin~~, [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,]and/or ~~other~~ **plant-based or other** ingredients which have been*

[proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. Infants from the 6th month on and for young children.

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

8.1 Key themes

8.1.1 Flexibility

We support the opinion of several eWG members that ensuring nutritional equivalence with cow's milk and including milk-based drinks in the compositional requirements for young children is important. Based on the same reasoning **plant-based alternatives to milk, such as whole bean soy drinks, should also be included.** We fully support that the proposed nutritional compositional requirements for follow-up formula for young children need to be flexible enough to accommodate highly formulated formula products, as well as products that are based on cow's milk, or are milk based drinks with the addition of key nutrients. In the same reasoning **plant-based alternatives to milk, such as whole bean soy drinks, should also be included.**

Therefore following changes are proposed:

*Several eWG members emphasised that nutritional equivalence with cow's milk and ensuring milk-based drinks **and plant-based alternatives to milk** can be considered and accommodated within the compositional requirements for young children is important. As follow-up formula is often used as a replacement for cow milk by young children, some eWG members were of the view that the composition of follow-up formula for young children may need adjustment where necessary to ensure that key nutrients from cow milk are provided (calcium, vitamins B2 and B12). It is difficult to ascertain from the eWG comments, whether this approach is aligned with (and would accommodate) the suggestion of some that the nutritional compositional requirements for follow-up formula for young children need to be flexible enough to accommodate both highly formulated formula products, as well as products that are based on cow's milk, or are milk based drinks, **or plant-based alternatives to milk**, with the addition of key nutrients.*

In summary, several considerations of flexibility emerged:

- *Flexibility to address nutrients of concern, which vary regionally,*
- *Flexibility in the nutrients mandated in the composition of formula for young children,*
- *Flexibility to enable fortified milk drinks and **plant-based alternatives to milk** to be covered within the standard*

APPENDIX 2 – PROPOSED DRAFT REVISION TO THE STANDARD FOR FOLLOW-UP FORMULA

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS (for older infants 6-12 months)

3.1 Essential composition

3.1.1 Follow-up formula

In regards to the proposed changes to the current definition 2.2:

***Follow-up formula** is a [food] OR [product] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,~~ [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. ~~infants from the 6th month on and for young children.~~*

In the definition all reference to plant-based products have been deleted while there is, based on the general comments mentioned above, a clear need for including plant-based products, such as whole soybean drinks in this definition.

Therefore the following changes are proposed:

*Follow-up formula is a [food] OR [product] ~~prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin~~, [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,]and/or ~~other~~ **plant-based or other** ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. Infants from the 6th month on and for young children.*

a) Proteins

Proteins are essential components of the diet supporting maintenance and growth requirements.

Calculation of the amount of protein in foods is typically performed using the conversion factor N x 6.25 and **allows for international harmonization** in the expression of protein levels.

The conversion factor 6.25 N is recognized by Codex Alimentarius (Codex Guidelines on Nutrition Labelling CAC/GL 2-1985) as appropriate conversion factor for determining protein content of soy product as well as by the European commission in EU regulation 1169/2011 on Food information to Consumers.

Recommendation: footnote 2)

> *For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. ~~\The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.~~*

c) Carbohydrates

The group carbohydrates contain poly-, di- and monosaccharides. The term 'sugars' is conventionally used to describe mono- and disaccharides[1]. The three principal monosaccharides are glucose, galactose and fructose which are the building blocks of disaccharides including sucrose, lactose, trehalose and maltose.

Evidence indicates that the metabolism of all mono- and disaccharides is similar regardless of whether they are present naturally (eg. lactose in milk, fructose in fruit) or whether they are added to a food. Therefore all sugars (mono- and disaccharides including lactose, fructose and glucose) provide the same amount of energy (4 kcal/g).

Based on the above there is **no scientific reason to indicate either glucose, lactose or any other sugar as the preferred sugar for young children**. Furthermore for older infants and young children with a lactase deficiency, the disaccharide lactose should be avoided in their diet.

As such we propose not to indicate a 'preferred sugar'.

Recommendation: footnote 9)

> *9) ~~Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein~~. Only precooked and/or gelatinised starches gluten-free by nature may be added. ~~[If needed, sucrose, fructose may be added provided the sum of these does not exceed ≤20% of total carbohydrate.]~~*

In conclusion

1. **Plant-based drinks as an alternative to milk** should be included and considered both in the definition of follow-up formula as in discussing specific requirements for **follow-up formula for young children.**
2. For the determination of nutritional protein a **conversion factor of N x 6.25** is the most suitable calculation factor for the majority of food categories, including soy products. No separate calculation factor should be used for these products. The conversion factor of N x 6.25 allows for international harmonization.
3. Regarding nutritional carbohydrate there is currently no scientific evidence of a difference in calorie intake of different sugars. As such **nor sucrose ,lactose or any other sugar should be put forward as 'preferred'** in young children foods and drinks. In considering the **total amount of sugars**, monosaccharides and disaccharides all need to be **treated in the same way**.

GOED - Global Organization for EPA and DHA Omega-3s

General Comments

GOED would like to underscore the importance of providing the right nutrients to non-breastfed children. Breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants. Therefore, breastmilk is the benchmark when setting the composition of follow-up formula, even when taking into account key nutrients provided by a progressively diversified diet. Quality and diversity of complementary foods vary depending on the country, local cultures, and accessibility of particular foods. For example, long-chain polyunsaturated fatty acids, such as DHA, are mainly provided through fatty fish which is not always widely accessible.

For some nutrients, as underlined by the chair and vice-chairs, the composition set in the Infant Formula standard is also valid for older infants. For others nutrients, nutritional needs may be different and therefore

[1] European Food Safety Authority (EFSA), Scientific opinion on dietary reference values for carbohydrates and dietary fibre (2010; 8(3):1462)

an adapted composition is necessary. In order to define which nutrients are key and therefore essential for optimal growth of older infants, scientific evidence is needed. We firmly believe that not only convincing evidence should be taken into account but also probable evidence should be assessed on a case-by-case basis given the precautionary principle. The fatty acids DHA and ARA are considered by FAO as conditionally essential for early development as well as for life-long health.[2] Thus said, the precautionary principle should be applied, and DHA and ARA should be part of the essential composition of follow-up formula for older infants.

Specific Comments

GOED has specific comments related to Recommendation 6 on DHA, ARA and EPA, as well as Recommendation 22 on optional ingredients.

Recommendation 6

GOED believes that DHA and ARA should be mandatory nutrients and added together due to their critical role in infants' healthy growth and development. The level of intake and the most common complementary foods do not provide sufficient quantities of DHA and ARA in most developing countries. In addition, metabolic pathways responsible for *in vivo* DHA and ARA synthesis from dietary precursors are competing for the same enzymes; therefore, it's of paramount importance to add both fatty acids in follow-up formula in a balanced manner.

At the same time, GOED understands the position taken by the chairs of the e-WG who need to find a consensus and therefore we appreciate Recommendation 6 for optional addition. If Recommendation 6 is accepted, we believe it's important to include a recommendation regarding the ratio between DHA and ARA or set a range of values for both. We support the inclusion of the footnote from the Infant Formula Standard as indicated in our comments concerning Recommendation 22.

In case DHA is mandatory, we support the setting of a minimum level. Our proposal would be to set the minimum level at 0.2% of fatty acids which is in line with the majority of levels in current regulations and standards world-wide.

We would like to emphasize that the addition of EPA in infant nutrition is not favored. In particular, EPA directly competes with ARA and is thought to be responsible for observations of growth faltering in infants fed DHA-alone formulas. Therefore, in infant nutrition, EPA content should not be too high. This is the reason behind the footnote in the Infant Formula Standard which limits the EPA content so it doesn't exceed the DHA content. Furthermore, this is linked to the fact that some Omega-3 sources such as fish oils contain both DHA and EPA. Other sources such as algal oils are mainly composed of DHA. We therefore believe that the reference to EPA as an optional addition should be deleted from Recommendation 6.

Recommendation 22

GOED has comments on 2 separate parts of Recommendation 22, namely wording under 3.3.2.2 and Docosahexaenoic Acid (and the DHA related note).

Wording under 3.3.2.2

We would like to emphasize our general support of the reference to human milk in the principle for addition of optional ingredients. As indicated in our general comments, breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants. Therefore, breastmilk is the benchmark for key nutrients. While we don't have a strong preference for the wording used for paragraph 3.3.2.2, we strongly support the reference to human milk be retained.

Therefore, we favor the following wording:

3.3.2.2 *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~,~~ **taking into account levels in human milk, as appropriate based on age and the desired contribution of human milk to the diet**.*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit,* ***taking into account levels in human milk.***

Docosahexaenoic Acid

As expressed in our general comments, as well as in our comments to Recommendation 6, we support mandatory addition of DHA and ARA. If DHA should remain optional; however, we agree with the GUL

[2]FAO Report 91 Fats and fatty acids in human nutrition: Report of an expert consultation. Available online at http://www.fao.org/3/a-i1953e.pdf

proposed for DHA and the footnote linking the use of DHA to ARA. The additional sentence on EPA is also needed in order to limit the intake of EPA as explained above in our comments to Recommendation 6.

DHA related note in case DHA is mandatory

In case DHA is mandatory, we support the setting of a minimum level. Our proposal would be to set a minimum level at 0.2% of fatty acids which is in line with a majority of levels in current regulations and standards world-wide.

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

Older infants and young children represent vulnerable groups with specific needs for food safety and quality with a continuum in the nutritional needs of older infants and young children. We agree that a number of nutrients can be found in the diet which increases in diversity between 12 and 36 months. However, a number of studies around the globe indicate, as shown in the last consultation paper, that some nutrients are frequently limited in the diet of older infants and young children. DHA is amongst those nutrients which are not sufficiently consumed. Limited intake of DHA has been acknowledged by a number of delegations. Given the crucial role of DHA not only during early development, but throughout life, we believe it should be part of the essential composition of follow-up formula for young children.

We would like to stress that newly available data (from Exponent, Inc. and provided to the WG by IFT in the first consultation earlier this year) suggests that not only are intakes of DHA low, but intakes of ARA may also be inadequate. Thus said, a provision of DHA and ARA may be beneficial in providing a valuable safety net, protecting the nutritional status of those young children with inadequate intakes of these key fatty acids.

EUVEPRO - European Vegetable Protein Federation

We are concerned that the proposed use of 5.71 as the nitrogen to protein conversion factor for soy instead of the widely accepted 6.25 factor represents a departure from current Codex Standards, the guidance of globally recognized scientific organizations, member country government regulations, and published scientific literature. This change would also have a significant negative impact on the perception of soy as a nutritious and high-quality protein, and we therefore kindly request:

1. The deletion of the third sentence in Footnote #2 of CODEX STAN 156-1987:

   Footnote 2

   2 For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. ~~The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.~~

2. The referral of the assessment of the appropriate nitrogen to protein conversion factor for soy to the Codex Committee for Methods of Analysis and Sampling (CCMAS). Nitrogen to protein conversion factors represents an analytical matter and we believe they should be referred to the appropriate Codex Committee with expertise in this matter. Referring the assessment to CCMAS would be consistent with the mandate the CCMAS received from the 38th CAC:

   FAO/WHO Coordinating Committee for Asia (CCASIA)

   Regional Standard for Non-Fermented Soybean Products

   21. Several delegations supported the proposal of the Secretariat to ask CCMAS to consider the appropriateness of the use of the conversion factor of 5.71 to determine protein content in soybean products in general.

   Conclusion

   22. The Commission agreed to:

   · Adopt the draft regional Standard at Step 8, subject to the endorsement of the food labelling provisions by CCFL as recommended by CCEXEC7013.

   · Ask CCMAS to assess the appropriateness of the use of the conversion factor of 5.71 to determine protein content in soybean products in general.

Please find as annex a summary of scientific and regulatory arguments to support the above requests. We plan to address this issue at the forthcoming CCNFSDU37 session and thank you very much in advance for taking our concerns into consideration.

Annex

Scientific and Regulatory Arguments

What is the origin of 6.25 ?

The Kjeldahl method, the modified Kjeldahl method, and the combustion method (known as the Dumas method) are commonly used for analytical measurement of protein. These methods measure protein in foods indirectly by assessing the quantity of nitrogen that can be released from a protein and captured as ammonia. Nitrogen from all nitrogenous compounds, including proteins and non-protein material, are typically included in this total. In the early 1880s, when the Kjeldahl method was invented, proteins readily available for testing (serum albumin and globulin from blood, casein from milk) contained about 16% nitrogen. Dividing 100 by 16% gave a nitrogen conversion factor of 6.25 and it was believed that this factor applied to all proteins. Although it has since been discovered through further scientific research that few foods contain precisely 16% nitrogen, use of the 6.25 conversion factor for measurement of protein sources has been maintained to allow for a measure of international harmonization in the expression of protein levels.

What is the origin of 5.71?

In 1931 (revised in 1941), USDA scientist D.B. Jones published a report ("Circular 183")[1] which proposed establishing unique nitrogen to protein conversion factors for several foods. Jones reported 5.71 as a more "precise" factor for soy protein. In this Circular[1], Jones hypothesized that not all nitrogen in foodstuffs was protein nitrogen and not all proteins contained 16% nitrogen; therefore, a universal conversion factor of 6.25 was not always appropriate. In support of his theory, Jones reported nitrogen contents for several plant and animal proteins from a variety of sources. Jones justified the 5.71 factor for soybeans by stating, **incorrectly**, that the major protein in soybeans is glycinin, a globulin composed of 17.5% nitrogen. From these data, he designated a conversion factor for soy protein of 5.71 (100 divided by 17.5 results in a factor of 5.71).

Glycinin (11S), however, represents only about 31-52% of the total protein in soybeans[2-4]. There are many other proteins in soybeans, including beta-conglycinin (7S), which represents about 35% of the total protein[2-4]. **If one considered only the 7S protein, the nitrogen to protein conversion factor for soy would be as high as 6.45**[3,4]. The ratios of 11S to 7S in soybeans will vary significantly, depending on the soybean variety and differences in seasonal growing conditions[2-4].

What is the Support for 6.25

The 6.25 nitrogen conversion factor is recognized by Codex Alimentarius as the appropriate conversion factor for determining the protein content of a soy product per the following Codex Standards:

- Codex Standard 175-1989 Codex General Standard for Soy Protein Products[5]
- Codex CAC/GL 2-1985 Guidelines on Nutrition Labelling (as amended by the 29th Session of the Commission, 2006)[6]
- Codex Standard 234-1999 Recommended Methods of Analysis and Sampling (as amended by the 30th Session of the Commission, 2007)[7]

Although an exhaustive list of regulations from around the globe was not assessed, the nutrition labeling regulations or regulatory product composition standards for the following countries representing a significant portion of the world's population list 6.25 as the N conversion factor for soy protein:

- Select National and Regional Government Nutrition Labeling Regulations
    - Argentina[8]
    - Brazil[9]
    - China[10] (for soy protein ingredients, isolated soy protein & soy protein concentrate)
    - European Union[11]
    - India[12]
    - Japan[13]
    - Korea[14]
    - Malaysia[15]
    - Mexico[16]
    - South Africa[17]
    - United States[18]

The following globally recognized analytical sciences associations identify 6.25 as an appropriate nitrogen conversion factor for soy in their current official analytical methods:

- American Oil Chemists Society (AOCS)[19-22]
- AOAC[23]
- AACC International (AACC)[24-27]
- International Organization for Standardization (ISO)[28]

Soy is a Source of High-Quality Protein

In addition, soy is a source of high quality plant protein, comparable to meat, milk, and eggs. Numerous nitrogen balance studies found soy protein is comparable to milk and meat in its ability to support N balance[29-34]. The 6.25 nitrogen to protein conversion factor was used by researchers to calculate gram amount for **both** soy and animal-based protein fed to study subjects. Rand, et al., 2003[35] conducted a meta-analysis of nitrogen balance studies that was used to estimate protein requirements for healthy adults and found soy protein is comparable to milk and meat in its ability to support nitrogen balance. Rand et al. stated, "These original soy studies showed clearly that the well-processed soy proteins were equivalent to animal protein, whereas wheat proteins were used with lower efficiency than were animal protein (beef)"[35].

The Protein Digestibility-Corrected Amino Acid Score (PDCAAS) is the currently accepted and validated method for protein quality measurement based on the principle that the nutritive value of a protein depends on its ability to provide amino acids in adequate amounts to meet the requirements of children and adults[36]. The PDCAAS for isolated soy protein and soy protein concentrate is equal to 1.0, comparable to milk and egg proteins[37,38].

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IDF – International Dairy Foundation

Recommendation 3

Minimum protein level

IDF would like to reiterate that consideration of the safe minimum content of protein needs to ensure that the product achieves the required indispensable amino acid profile and with adequate “bioavailability”, i.e. protein quality.

The importance of nutritional quality is highlighted in the current Standard:

“Not less than 3.0 g per 100 available calories (or 0.7 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality [1] of the protein shall not be less than 85% of that of casein…”

[1] Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.

Hence, for such a vulnerable population groups for whom follow-up formula (FUF) (6-12 months) is a predominant source of nutrition and high quality protein, protein content cannot be considered in isolation of protein quality. And this should be done in consideration of new international recommendations.

There is some recognition of the view that while the factorial method has been used for the USDRIs(2005) and the FAO/WHO (2007) safe intakes, this approach has been questioned more recently, and using more sophisticated methods such as the Indispensable Amino Acid Oxidation methods which may give higher estimates of requirements (Elango et al 2012).

The assessment of protein quality in the current Follow-up Formula Standard is determined by the protein efficiency ratio (PER). The PER method is a bioassay in rats and is considered out of date and of limited value in evaluating the suitability of proteins for infant feeding. Since the development of the Follow-up Formula Standard, a Joint FAO/WHO Expert Consultation on Protein Quality Evaluation recommended the use of the Protein Digestibility Corrected Amino Acid Score (PDCAAS) to determine protein quality. The recommendations of the Joint FAO/WHO expert consultation (1989) informed the Infant Formula Standard which is based on the amino acid content in breast milk as the reference protein.

More recently, in 2013 an FAO Expert Consultation on dietary protein quality was held. The expert consultation provides an update and improvements to the PDCAAS method for measuring dietary protein quality, referred to as Digestible Indispensable Amino Acid Score (DIAAS). The key findings of the report that relate to the Codex review are that dietary amino acids should be treated as individual nutrients, and that for regulatory purposes two amino acid scoring patterns are recommended: birth to six months; and 6-36 months, and that if protein quality of FUF needs to be assessed then the most up-to-date method should be used.

Appropriate amino acid intake is an important consideration in the context of FUF for older infants. We note that cow's milk protein has high amino acid value and thus modified cow's milk is an appropriate base for a fortified product for consumption by older infants and young children.

It is noted that the FAO Expert Working Group's report, "Research approaches and methods for evaluating the protein quality of human foods" (2014) recommended the adoption of the DIAAS method by Codex. It is also recognised that there is further work to be completed to ensure a supporting framework to enable full implementation of the DIAAS method. Footnotes regarding protein quality should be amended at such time as implementation of this method becomes viable on development of the supporting framework.

To conclude IDF submits that protein quality should be mentioned in the Standard and with a reference to the method of analysis.

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Maximum Protein level

IDF supports the eWG Chair's recommendation for a maximum protein level in Follow-up Formula 6-12 months of 3.5 g protein/100 kcal.

Footnote 2

IDF supports the eWG Chair's recommendation to include footnote 2 as stated in the Infant Formula standard.

IDF reiterates the rationale provided to the electronic working group:

In 2006 following the extensive discussion on the use of specific protein factors, IDF undertook a comprehensive review of the scientific literature on nitrogen conversion factors. This has been published under the title "Comprehensive review of scientific literature pertaining to nitrogen protein conversion factors ". The publication (ref. Bulletin of the IDF no. 405/2006) is available for free download from the IDF Internet homepage: http://www.fil-idf.org/Public/PublicationsPage.php?ID=27121#list

The IDF review identified the following conversion factors (NCFs) for the two sources of protein:

- **milk proteins: 6,34 to 6,38**
- **soy proteins: 5,7 to 5,8**

The published scientific data provide a wealth of evidence and justification for the use of different NCFs for milk protein and soy protein. IDF was not able to find any scientific data justifying the use of a single NCF of 6,25 for milk protein and soy protein.

A review of the scientific literature published since 2006 has not yielded any new scientific evidence that would justify the use of a single NCF of 6,25. Hence, the conclusions of the IDF Bulletin of 2006 still stand and for this reason it is important to keep the footnote as in the IF Standard.

We would like to point out some further information and justification for the use of the scientifically established NCFs for the two main protein sources in formula for consideration by the members of the EWG.

Knowledge on primary structure of milk proteins and soy proteins and application in formula

1. Nitrogen conversion factors for the various milk proteins

The complete primary structure of the main milk proteins is known and internationally recognized (Farrell et al., 2004). This knowledge enabled Karman and van Boekel (1986) and later van Boekel and Ribadeau-Dumas (1987) to determine, with a high degree of precision, the NCFs for most protein fractions occurring in milk (99.5 %) (See Table1).

Table 1 : Nitrogen conversion Factors of various milk proteins, according to van Boekel and Ribadeau-Dumas (1987)

Product / protein	NCF (with carbohydrates)	% of each protein / total protein in milk
αs1- casein	6.36	30.3%
αs2- casein	6.29	7.9%
β- casein	6.37	28.2%
κ-casein	6.35	10%
γ-casein	6.34	2.4%
β- Lactoglobulin	6.29	9.7%
α- Lactalbumin	6.25	3.6%
Serum albumin	6.07	1.2%
Proteoses peptones	6.55	0.9%
Immunoglobulins	6.20	2.4%
Milk	6.36	
Isoelectric (Acid) casein	6.36	
Rennet whey proteins	6.41	

Note: Proteins are defined as a sequence (determined by the organism's genome) of amino-acids bound by covalent bounds (primary structure) and to which carbohydrate groups can be also attached by covalent bounds. These side groups are considered to constitute parts of the protein, not only because they are covalently bound to the amino-acid chain but also for their technological, nutritional and physiological functions.

The NCFs obtained by taking into account the known sequences of all the individual proteins with their lateral groups and their proportions in milk are as follows:

- 6.36 for natural milk protein, a value that is very close to the historically used value of 6.38 (Hammarsten, 1883);
- 6.36 for casein (isoelectric casein is the casein being effectively used for this type of formula)
- 6.41 for whey protein (most of the whey protein in formulas is whey proteins derived from renneted milk).

Accordingly, the NCFs that must be used for protein fractions of milk-based formulae are 6.36 for the casein part and 6.41 for the whey protein part.

2. Nitrogen conversion factors for milk-based formula

On the basis of the figures of Table 1 of the Appendix, the NCFs for milk-based formulae were calculated for different whey protein to casein proportions that are used in formula. These respective calculated values can

be found in Table 2.

Table 2 : Nitrogen conversion factors for different formulations of milk infant formulas currently available, using values of Table 1, calculated by Maubois (INRA France) for different formulations of milk infant formulae (2006, unpublished work)

Proportion in infant formula Whey protein (6,41) / isoelectric casein (6,36)	Conversion factor for the infant formula
20 / 80	6,370
30 / 70	6,375
50 / 50	6,385
60 / 40	6,390

(Calculation example: 60/40 whey/casein formula : (60 x 6.41 + 40 x 6.36) / 100 = 6.39)

The results clearly show that regardless of the relative proportions of whey proteins and casein in milk-based formula the nitrogen conversion factor remains close to the value of 6.38.

In conclusion, the scientific knowledge about the primary structure of milk proteins (Table 1) as well as data on milk proteins used in formula (Table 2) justifies the use of the internationally recognized NCF of 6.38 for milk protein for formulae.

1. Nitrogen conversion factors for soy-based formula

Soy (Glycine max) proteins, mostly globulins, are distinguished according to their sedimentation coefficients into globulins 7 S (or β conglycinin), globulins 11 S (or glycinin) and globulins 2S. Globulins 7S and 11S account both for more than 80 to 90% of total protein content. The ratio 11 S/7 S varies between 0.5 and 1.7, according to the cultivars (Utsumi, 1992).

The first NCF proposed for soy proteins was 5.71 (Jones, 1931). It was calculated from the nitrogen determinations performed by Osborne and Campbell (1898) on soy protein extracts. Then, for no known scientific reason other than a theoretical 15 % nitrogen content in all protein sources, the value of 6.25 was agreed for all vegetable proteins and applied for soy proteins. This occurred despite the fact that ever since 1946, this value was considered too high, in view of the studies performed on soy isolates (Smiley and Smith, 1946, Smith and Circle, 1972, Mossé, 1990, Sosulski and Imafidon, 1990). Tkachuk (1969) suggested the NCF of 5.69 for total proteins contained in defatted unhulled soybean flour. Mossé (1990) determined a NCF of 5.52 ± 0.02 from the amino acid profiles of 6 samples of soy protein powders.

From the described sequences of the main soy protein fractions (Utsumi, 1992), Lorient (2006, unpublished work) calculated the different NCFs detailed in Table 3.

Table 3: Nitrogen conversion factors for soy protein calculated on the base on knowledge of primary structure (Utsumi, 1992) for different fractions of soy proteins calculated by Lorient (2006, unpublished work)

Product / protein	NCF
β– conglycinin (α') (7S)	5.58
β– conglycinin (α) (7S)	5.65
β– conglycinin (β) (7S)	5.66
Glycinins (mean value of the 5 subunits) (11S)	5.56

Given the variability of the relative proportions between Glycinin (11S) and β-conglycinin (7S), 0.5 to 1.7 (Utsumi, 1992) in the cultivars, it is not easy to calculate a mean NCF but the calculated values of Table 3 lie in a very narrow range. One can therefore consider that the NCFs in all soy cultivars vary between 5.56 and 5.66 leading to a mean value of 5.61.

However, the value of 5.61 does not take into account the covalently bound side groups. According to Utsumi et al. (1997), the three subunits of the β-conglycinin (7S) are glycosylated (Koshiyama, 1969) as well as the hemagglutinin component (Lis et al., 1966) which amounts to 3 % of soy flour (Liener and Rose, 1953). Thus, taking into account the glycosylated part of 7S, the glycosylation of hemagglutinin and the various 7S/11S ratios, the calculated NCFs for the different soy cultivars are varying between 5,69 and 5,79 (see Table 4).

Table 4 : Nitrogen conversion factors of different soy cultivars taking into account the glycosylated part of 7S and the glycosylation of hemagglutinin (Utsumi et al., 1997, Koshiyama,1969, Lis et al., 1966) calculated by Lorient (2006, unpublished work)

Ratio 11 S / 7 S	NCF
0,5	5,79
1	5,73
1,5	5,69

The calculated values for soy protein in Table 3 and Table 4 confirm the figure given in the literature (5,71) also taking into account the slight variability depending on the cultivar. The use of a NCF of 6.25 for soy proteins is not scientifically justified. It leads to an overestimation of protein content of between 8 and 10 %.

In conclusion:

- The published scientific data on milk protein, including the knowledge about the primary sequence of milk proteins, demonstrate that the nitrogen conversion factor of 6,38 for milk protein is justified in case of either total milk protein or milk protein used in formula.
- According to scientific data, the appropriate nitrogen conversion factor for soy protein is 5,71.
- The proposed introduction of a single arbitrary nitrogen conversion factor (NCF) of 6,25 for all protein sources in the Codex Standard for Follow-up-Formula cannot be justified on the basis of the available scientific data. Such a factor does not take into account the enormous research work of the past 50 years aiming at improving the knowledge about proteins as essential nutrients for human beings as well as their differences in terms of amino acid composition and their specific nutritional quality.
- Compositional requirements in Codex standards must be verifiable for official food control purposes through international analytical standard methods of sampling and analysis as have been endorsed by the Codex Committee on Methods of Analysis and Sampling. A single arbitrary nitrogen conversion factor of 6,25 would result in an underestimation by about 2% of the actual protein content in milk-based formula and a serious overestimation of the content of soy by approximately 8-10% in soy-based formula.
- The scientifically established nitrogen protein conversion factors for milk protein of 6,38 and for soy protein of 5,71 should be applied in the Codex Standard for Infant Formula according to the established recommendation on use of a specific nitrogen protein conversion factor when such a specific factor is known (FAO 1970) and (FAO 2003).

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IFT - Institute of Food Technologists

IFT thanks the chairs of the electronic working group for the review of the standard for follow-up formula (CODEX STAN 156-1987), as several productive rounds of work have been completed. We offer comment on the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNSFDU) on the topic as it relates to essential composition of follow-up formula.

(i) General comments

As a general and preliminary comment IFT supports breastfeeding of older infants and young children, as breast milk is an ideal food for the healthy growth and development of infants. Pragmatically, however, in situations where breastfeeding is not possible for a variety of reasons, we believe it is important to provide alternate food products with the most comparable nutrient profile to breast milk as possible. We strongly believe that breast milk composition is the gold standard to which formulation should be held and that breast milk is the benchmark when setting the composition of follow-up formula, even when key nutrients are provided by a progressively diversified diet. Quality and diversity of complementary foods varies among countries and within local cultures, and is clearly influenced by accessibility of particular foods. For example, long-chain poly-unsaturated fatty acids (LCPUFA) such as DHA (22:6, n3) are mainly provided through fatty fish, which is not always widely accessible. Even the LCPUFA ARA (20:4, n6) that is always present in breast milk [1], may be limited in its dietary availability if meat or eggs are not consistently provided as dairy milks are nearly void of this important nutrient [2]. Breast milk is a product that has evolved to specifically support optimal outcomes for the human infant [3], its composition serves as the best evidence for composition. The fatty acids DHA and ARA are considered by FAO as conditionally essential for early development as well as for life-long health [4]. The lack of preformed ARA and DHA in dairy milk [2] as opposed to human milk, as well as the milk of other primates [5], is distinctive.

Specific comments

IFT supports recommendations 1, 2, and 5. We have specific comments in relation to recommendations 6 on DHA, ARA, and EPA, recommendation 8 on vitamin A, recommendation 9 on vitamin D, and recommendation 22 on optional ingredients.

Recommendation 6

As expressed in our comments within the eWG, we firmly believe that DHA and ARA should be mandatory and added together due to their critical role in infants' healthy growth and development. Breast milk is often the primary source of ARA and DHA in the diets of older infants and young children. Amounts of these fatty acids provided by complementary foods are often substantially less and inadequate to compensate for the lack of breast milk. As conveyed to the eWG, IFT members working for DSM and Exponent used databases maintained by FAO, WHO, USAID that report food intake as well as breastfeeding durations in multiple regions of the world as well as other peer reviewed publications to develop estimates of ARA and DHA intakes by older infants and young children as part of a manuscript (*in preparation*). These studies found that in exclusively breast fed infants, the measured mean breast milk intake at 6 months was 854 g/day [6], and based on that data, and an estimation that 4.2 % of breast milk is composed of fatty acids [1, 2], the average ARA and DHA intakes in exclusively breast fed infants at age 6 months are estimated to be 165 mg/day and 93 mg/day respectively. Moreover, most of infants that continue to receive breast milk were estimated to consume in the range of 600-900 g of breast milk per day through 12 months of age [6]. Consumption of that amount of breast milk would provide those infants with an ARA intake of 116-174 mg/day and DHA intakes of 66 – 98 mg/day from breast milk.

It is often thought that conversion of precursor fatty acids LA (18:2, n6) and LNA (18:3 n3) is a sufficiently active metabolic pathway to provide requisite amounts of ARA and DHA, respectively, if given to young children at suitable concentrations through formula products. However, metabolic conversion rates drop as infants mature into young children and LA/LNA supplementation does not maintain circulating concentrations of ARA and DHA [7, 8]; interestingly ARA and DHA concentrations in breast milk do not drop during this period of time [9] and likely cover the amounts lost due to reduced precursor conversion. Even in healthy infants, the endogenous synthetic capacity for

both DHA and ARA declines dramatically [10], and evidence supports the need for additional intake of both ARA and DHA to maintain plasma concentrations [11]. It has been demonstrated that direct provision of DHA and ARA supports DHA and ARA blood levels throughout the first year of life more sufficiently than provision of even higher than standard levels of the DHA and ARA precursor molecules (i.e., LA and LNA) [12].

Nevertheless, it is of paramount importance to add both precursor fatty acids to follow-up formula in a balanced manner as both LA and LNA compete for the same enzymes within the conversion pathway [13].

Currently the chairs of the eWG propose a consensus seeking outcome within recommendation 6 where addition of DHA is optional. While IFT does not believe that recommendation 6 will provide best nutritional benefit for consumers of follow-up formula, we would further recommend that if recommendation 6 is accepted there must also be a recommendation with regards to the ratio between DHA and ARA within the final product and provide a range of values for amounts to add for both fatty acids. We support the inclusion of the footnote from the Infant Formula Standard as indicated in our comments to Recommendation 22.

In the event that DHA is mandatory, IFT supports the setting of a minimum at 0.2% of fatty acids which is in line with a majority of current recommendations. IFT would also draw the committee's attention to possible detrimental effects of EPA (20:5, n3) as a direct competitor for ARA that is thought to be responsible for observations of growth faltering in infants fed DHA-alone formulas. Indeed this is the reason behind the footnote in the Infant Nutrition Standard which limits the EPA content to no more than that of DHA. We therefore believe that the reference to EPA should be deleted from recommendation 6.

VITAMINS AND MINERALS

Recommendation 8

IFT supports retention of the minimum vitamin A level; however we disagree with aligning the maximum level with the Standard on Infant formula. Vitamin A is highly important to combat infection and blindness. The current maximum level of vitamin A (225 µg RE/100 kcal and 54 µg/100 kJ) has shown a history of safe use (21CFR 107.100)**Error! Hyperlink reference not valid.** and should be retained.

Recommendation 9

Vitamin D is key for the development of bones and also important for many metabolic pathways. A Recognized Authoritative Scientific Body (RSAB) for the eWG, the European Food Safety Authority (EFSA) recently raised Vitamin D concentration recommendation to 2 µg/100 kcal based on a large body of evidence indicating benefits of higher intakes than previously recommended. In addition, the prevalence of inadequate intake is high even in countries with a lot of sun and for this reason IFT supports setting a higher maximum value in order to allow flexibility for national authorities to set values appropriate for their country. In its 2012 opinion, EFSA set a Tolerable Upper Safe Level at 25 µg/day for infants from 0 to 1 years of age. Setting a maximum value at 4.5 µg/100 kcal thus allows intakes to remain below this value within a daily consumption of 500 kcal as follow up formula.

Recommendation 22

IFT has comments on 2 separate parts on recommendation 22, namely wording under 3.3.2.2 and Docosahexaenoic Acid (and the DHA related note).

Wording under 3.3.2.2.

IFT once again notes that breast milk should be the gold standard to which follow-up formula composition is based and be used to guide the addition of optional ingredients. As indicated in our general comments, breastfeeding is an ideal food for the healthy growth and development of infants. Therefore, breastmilk is the benchmark for key nutrients. We do not have a preference for the wording used for paragraph 3.3.2.2., except the fact that we strongly support the reference to human milk be retained.

Therefore IFT supports the following wording:

3.3.2.2 *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~,~~ **taking into account levels in human milk, as appropriate based on age and the desired contribution of human milk to the diet**.*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit,* ***taking into account levels in human milk.***
Docosahexaenoic Acid

As expressed in our general comments and specific comments in regards to Recommendation 6, IFT supports the mandatory addition of DHA and ARA. However, if DHA should remain optional, we agree with the GUL proposed for DHA and the footnote linking the use of DHA to ARA. The additional sentence on EPA is also needed in order to limit the intake of EPA as explained above in our comments to Recommendation 6.

DHA related note if DHA is mandatory

In the event that DHA is mandatory, IFT supports the setting of a minimum at 0.2% of fatty acids which is in line with a majority of current recommendations.

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

Older infants and young children represent vulnerable groups with specific needs for food safety and quality with a continuum in the nutritional needs of older infants and young children. IFT agrees that a number of nutrients can be found in the diet as it increases in diversity between 12 and 36 months. However, a number of studies around the world indicate, as shown in the last consultation paper, that some nutrients are frequently limited in the diet of older infants and young children. DHA is amongst those nutrients which are not sufficiently consumed.

Limited intake of DHA has been acknowledged by a number of delegations. Given the crucial role of DHA not only during early development but throughout life (note the committee's current work on DHA/EPA NRV-NCD, agenda item 7). On this basis IFT believes that DHA, and as a result the balanced addition of ARA, should be part of the essential composition of follow-up formula for young children.

In part IFT's viewpoint has been powerfully guided by new work of members who have data mined publicly accessible databases and peer-reviewed literature to compile new knowledge through the synthesis of breastfeeding rates, household food intake patterns, and food and breast milk composition, to document an underappreciated deficit in DHA and ARA intakes in vulnerable young children. This work is in the process of being evaluated by peer-review and may be available for general distribution by the meeting date in late November. IFT members have shared this information within the confidential work of the eWG. In particular IFT would draw the attention of the committee to the integrated approach to health improvement that is possible through nutrition most notably in the prevention of chronic disease. The earlier this prevention begins the more effective it is. Again, breast milk or breastfeeding is best, but for those young children who are not receiving the benefit of breastfeeding, the availability of products formulated to closely match breast milk is highly desirable and precludes the creation of a "second-class" nutritional status in young children who are not breastfed.

IFT supports flexibility in the composition for essential vitamins and minerals that may vary in dietary provision (i.e., lack) in each part of the world. We also support the proposal to align this composition with the levels of follow-up formula for older infants.

The proposal to add optional ingredients on the basis of safety and scientific evidence allows for additional adaptation to the nutritional and physiological needs of young children. Advances in analytical and computational capacities have sparked significant advances in our understanding of breastmilk composition and physiological functionality [14-16]. IFT expects to revisit infant and follow-up formula recommendations particularly in regard to carbohydrate and protein composition where new information related to bodyweight regulation and microbiota improvement is too recent to be adequately addressed in this round of revision.

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ISDI – International Special Dietary Foods Industries

General Comments

WHA Resolution	At this step of the discussion, it is not part of the terms of reference of the 2015 eWG as agreed at the last CCNFSDU. ISDI considers it is not appropriate to make a reference to the WHA Resolution 39.28 in a revised Codex Standard for Follow-up Formula. Inclusion of WHA resolutions is not consistent with other Codex Standards.

JUSTIFICATION

The WHA resolution 39.28 refers to "*the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary"*. Any recommendation about "*feeding practices*" may be part of a Guideline or a Code of Practice, even though this approach would be exceptional in as generally Codex Guidelines and Code of Practices are about technical matters (e.g. principles, inspection, risk analysis, hygiene, prevention of contamination, etc.), rather than practices.

The resolution is clearly referring to the practice of introducing follow-up formula too early, which should not be the case when the instructions for use are being followed.

In this context it is important to emphasize that the WHA Resolution 39.28 was adopted in 1986 prior to the adoption of the Codex Standard for Follow-up Formula (Codex STAN 156-1987). Hence it is appropriate to assume that the data reported in the Resolution are not reflective of the current global environment in which follow-up formula are regulated either along the Codex STAN 156-1987 or comparable national regulatory provisions.

Specific Comments

DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)	ISDI COMMENTS
2. DESCRIPTION **2.1 Product Definition** **2.1.1 Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~ [a) the liquid part of the diet for older infants when complementary feeding is introduced; and b) a liquid part of the progressively diversified diet of young children.] **2.1.2 Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold]. OR **Follow-up formula** is so processed ~~by physical means~~ only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] and distribution [and sale] in the country where the product is sold]. **2.2 Other Definitions** 2.2.1 The term **infant** means a person of not more than 12 months of age. 2.2.2 [**Older infants** means persons from the age of 6 months and not more than 12 months of age.] 2.2.3 The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months). Please note that the above proposed structure and approach for Section 2 would see current definitions 2.2 moved to Section 3 – Essential Composition. The Chairs propose the following amended drafting for consideration: ***Follow-up formula*** *is a [food] OR [product] prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, [based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. infants from the 6th month on and for young children.* The following statements have also been proposed (in addition to that above) for consideration by the	ISDI's preference is to have the basic definition at the beginning of the standard but can accept the repositioning proposed for current definition 2.2 to be moved to Section 3 and for current definition 2.4 to be moved to Section 9.5. **2. ~~DESCRIPTION~~ DEFINITION** **2.1. Product definition** **2.1.1** ISDI supports the recommendation of the eWG Chair proposal for the definition that separates the two product categories: older infants on the one hand and young children on the other hand. This allows clarifying the separate product categories with their respective role and purpose in the diet. ISDI recommends replacing "the" by **"a"** in a) for better alignment with the overarching definition ("a food") and with wording of (b): [a) ~~the~~ **a** liquid part of the diet for older infants when complementary feeding is introduced; and **2.1.2** This paragraph could be transferred to the beginning of Section 3. Both options proposed include "*in the country where product is sold*." This seems inappropriate as follow-up formula products need to meet the specific mentioned criteria independent of the country where the products are manufactured or sold. ISDI's proposal will read : **[Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution** ~~[and sale] in the country where the product is sold~~"] **2.2.** ISDI proposes that the definitions are maintained under 2.2 "Other definitions" similar to the Codex Standard for Infant Formula.

Committee, if the inclusion of the concept of 'supporting growth and development' is deemed necessary. *[The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.]* OR *[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].*	

JUSTIFICATION

ISDI welcomes the eWG Chair's proposal to include the two product-categories in the definition (2.1.1).

As expressed in CP1 and CP2, the view of ISDI view is that it seems better to have basic definitions and descriptions at the beginning of the standard. However, ISDI could align with the modifications proposed by the eWG Chair for proposed definitions 2.2 and 2.4.

The recommended change to delete the text in 2.1.2, "*in country where product is sold,*" is to acknowledge that follow-up formula products need to meet the specific mentioned criteria independent of the country where are sold.

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS

(6-12 MONTHS)

RECOMMENDATION	ISDI COMMENTS
Recommendation 1 (Section 6.1)	ISDI supports the recommendation of the eWG Chair.
Recommendation 2 (Section 6.1)	ISDI supports the recommendation of the eWG Chair, but notes that there is inconsistent use of significant figures in the draft revised Codex Standard for Follow-up Formula.
Recommendation 3: Minimum and maximum levels for protein (Section 6.2.1)	**Minimum Protein Level** ISDI supports a minimum protein level at 1.65 g/100 kcal. Appropriate scientific substantiation and as needed clinical evaluation is required to determine the suitability of follow-up formula for older infants with a protein content between 1.65 and 1.8 g/100 kcal. **Maximum Protein Level** ISDI supports the eWG Chair's recommendation for a maximum protein level of 3.5 g/100 kcal in follow-up formula for older infants. **On footnote 5:** ISDI supports the inclusion of the text in square brackets and recommends the wording of footnote 5 is further amended to reflect this inclusion to read: "*5) The minimum value applies to cows' **and goats'** milk protein. For Follow-up Formula based on ~~non cows' milk~~ protein **from other animal origin,** 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) **should apply**.*" **On footnote 6:** Footnote 6 should be replaced by:

	Milk based [Follow-up formula ~~based on non-hydrolysed milk protein~~ containing less than **[**~~2~~ **1.8** g protein/100 kcal**]** ~~and~~**]** ~~infant [formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal]~~**]** should be **scientifically substantiated and as needed,** clinically evaluated**]**

JUSTIFICATION

Minimum Protein Level

ISDI supports a minimum protein level at 1.65 g/100 kcal.

- The protein minimum requirement is set to cover maintenance and growth. Recent estimates of protein requirements are lower than previous estimates, primarily as a result of changes in the reference body weights that were previously used (WHO/FAO/UNU 2007). EFSA (2013) adopted the same approach in its report "*Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union*".
- An expert group coordinated by the Early Nutrition Academy (ENA, 2012) recommends setting the minimum content of cow's milk protein in follow-up formula at 1.65 g/100 kcal, based on a good protein quality an adequate content of essential amino acids.
    - The minimum protein content proposed by ENA (1.65 g/100 kcal) has been derived from;
        - Daily reference values for proteins;
        - Population reference intakes for dietary protein intake calculated to meet the needs of basically all infants in the population with an adequate safety margin;
        - Complementary feeding and family foods providing 10-15% of energy as protein.
    - Safety and suitability of a formula with a protein content of 1.65 g/100 kcal has been scientifically demonstrated.
        - Ziegler *et al.* (2015) demonstrated that growth of infants between 3 and 12 months fed a high quality protein formula with a protein level of 1.61 g/100 kcal was adequate.
        - Similarly, growth was assessed between 3 and 12 months for a 1.65 g protein/100 kcal in a specific population of infants born to overweight mothers (Inostroza, 2014).
        - Hence data from both studies indicate that a protein level of 1.65 g/100 kcal is safe and suitable to support adequate growth in older infants.
- As recognized as safe, this low level will allow, while keeping benefits of follow-up formula, to introduce into the diversified diet other protein sources while still maintaining protein intakes that are similar to minimum protein requirements. Several national and regional representative surveys (e.g. Thailand, Mexico, Australia, Malaysia) (CX/NFSDU 14/36/7, 2014). In the Feeding Infants and Toddlers Study (FITS, 2008), the average protein intake for infants aged 6 to 11 months was above the reference (Butte, 2010).

Conclusion

For all the reasons mentioned above (protein requirements, ENA recommendations and, substantiated safety and suitability), ISDI support a decrease of the minimum protein requirement to 1.65 g/100 kcal.

Maximum Protein Levels

ISDI supports a maximum protein level of 3.5 g /100 kcal.

A) Science context

The scientific evidence is inconclusive to support an exact maximum for protein levels in follow-up formula for older infants, nor an upper limit for protein for older infants, as acknowledged by both EFSA (2014) and the WHO/FAO (2007). The maximum proposed protein level of 3.5 g/100 kcal is safe and suitable for consumption by older infants, has a long history of apparent safe use and has been globally marketed since the origin of the Codex Standard for Follow-up Formula (Codex STAN 156-1987).

- Maximum protein values that have been proposed for follow-up formula for older infants are based on an extrapolation from minimum protein requirements for older infants, rather than specific data that clinically supports a maximum level.
- Protein requirements for infants and young children (WHO/FAO, 2007) are defined as the minimum

intake that will allow nitrogen equilibrium at an appropriate body composition during energy balance at moderate physical activity, plus the needs associated with the deposition of tissues consistent with good health.

- The WHO/FAO (2007) highlights that the definition of protein requirement based upon nitrogen balance does not identify the optimal level of protein for long term health "*It is acknowledged that this definition of the requirement in terms of nitrogen balance does not necessarily identify the optimal intake for health, which is less quantifiable*". "*Current knowledge of the relationship between protein intake and health is insufficient to enable clear recommendations about either optimal intakes for long-term health or to define a safe upper limit*".
- The proposed upper level of protein of 3.5 g/100 kcal would provide 14% of total energy from protein. This falls within the range of protein typically consumed for 6-12 month infants within Europe, which is reported to be around 10-15% of total energy (Lagström *et al*., 1997; Noble and Emmett, 2001; Hilbig, 2005; de Boer *et al.*, 2006; DGE, 2008; Fantino and Gourmet, 2008; Marriott *et al.*, 2008; Thorsdottir *et al.*, 2008; Lennox *et al.*, 2013; EFSA, 2014). In the US, Butte *et al.* (2010) found that protein intake as a percentage of energy increased with age in the Feeding Infants and Toddlers Study (FITS), and that intakes were within the IOM (2002) Acceptable Macronutrient Distribution Range (AMDR) of 5-20% of energy. The range of protein intakes in US infants 6 to 11 months was wider at 7-13% of energy (for 10th and 90th percentiles, respectively) compared to that reported for older infants 6 to 12 months in Europe.
- Moreover, 14% of energy falls within the recommended protein intake set by different institutes (Nordic Council of Ministers and the Dutch Health Council) for 6 to 11 month old infants.

B) Measured & Appropriate Changes Context

Follow-up formula can form a very substantial proportion of the diet of older infants and, as such, can greatly influence their overall health and well-being. Therefore it would make sense to reduce the protein maximum gradually to ensure a stepwise approach to formulation changes that can be applied everywhere and takes global differences in protein intakes into account. A reduction in protein level from 5.5 g to 3.5 g/100 kcal will better help achieve this goal.

C) Trade and Consumer Confidence Context

A maximum protein level of 3.5 g/100 kcal for follow-up formula for older infants better facilitates the continued international trade of follow-up formula products, in comparison to other maximum values considered by the eWG;

- Currently the minimum level for protein in the existing Codex Standard of Follow-up Formula (CODEX STAN 156-1987) is at 3.0 g /100 kcal. Consideration of a proposed maximum protein level of 3.0 g/100 kcal, or lower, results in a protein range in the revised Standard that is mutually exclusive from the current range. Taking such an approach will mean that all follow-up formula products currently available globally will not comply with the protein requirements in the revised Codex Follow-up Formula standard, and further that manufacturers legally must continue to supply non-compliant product until such time as national jurisdictions amend their requirements to align with the new Codex standard. This could result in confusion and a resultant lack of confidence by consumers. There is no justification to undermine the perceived suitability of existing products in this way. It would be much more preferable for manufacturers to have the ability to reformulate products to comply with the protein requirements specified in the revised Codex standard without the need to wait for regulatory changes to apply. If the maximum protein level is set at 3.5 g /100 kcal it will allow manufacturers to reduce the protein levels to between 3.5 and 3.0 g protein/100 kcal (with the latter being the current minimum applied by most jurisdictions) immediately as a first positive step towards reducing protein levels.
- Reduction of the protein maximum from 5.5 g to 3.5 g protein/100 kcal is still a substantial shift and will result in reformulation with a focus on further reducing protein levels. Aiming for a reduced and wider protein range (1.65 to 3.5 g protein/100 kcal) allows this change to occur in a more measured and monitored way.
- A new protein maximum that is mutually exclusive from existing Codex requirements poses a significant risk of trade barriers. Therefore the proposed protein maximum of 3.5 g/100 kcal will resolve this and can form the basis of regulations applied by National Jurisdictions.

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Hydrolysed protein:

ISDI requests to continue to use hydrolysed protein as an adequate source of cow milk protein in follow-up formula for the following reasons. These formulas fed to older infants are recognized safe and suitable.

Several studies have shown that formulas based on partial protein hydrolysates support adequate growth (Vandenplas 2014).

In 2005, EFSA provided a scientific opinion on the suitability of an infant and follow-up formula based on partial protein hydrolysates with a protein content of 1.86 g/100 kcal. The Panel concluded that "*the formula is as suitable to satisfy the particular nutritional requirements of young infants and as safe as a*

formula based on hydrolysed whey protein with a higher protein content when fed ad libitum." (…) The Panel considered that "*a formula with this protein formulation is suitable for use in older infants in conjunction with complementary foods*" (EFSA, 2005). As a consequence of this scientific opinion, the EU Directive 2013/46/EU amending Directive 2006/141/EC with regard to protein requirements for infant formulae and follow-on formulae permits manufacturing from protein hydrolysates.

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Inclusion of goat's milk in footnote 5:

The EFSA 2014 report, "*considers that cow's milk protein, goat's milk protein and isolated soy protein (ISP) are safe and suitable protein source for Infant Formula and follow-up formula based on intact protein. The use of other protein sources in IF and FOF and/or the introduction of new technologies need clinical evaluation and their safety and suitability should be established in the target population prior to their general use in IF and FOF*."

This EFSA position on goat's milk protein adopts the conclusions of the EFSA 2012 report referenced below which deals specifically with the topic of goat's milk protein suitability as a source of protein for infant and Follow-on Formulas.

Given the peer-reviewed clinical evaluation that has been done on formulas based on goat's milk ISDI supports, "c*ow's milk*", in footnote[s] 5 [and 6] being replaced by, "*cow's and goat's milk*".

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RECOMMENDATION 4: LIPIDS (Section 6.2.2)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair.
JUSTIFICATION	
ISDI supports the recommendation of the eWG Chair that the total fat minimum and maximum level, including footnotes 7 and 8, should be revised and aligned with the Codex Standard for Infant Formula as there is no scientific reason to differentiate the fat content/quality of infant and follow-up formula for older infants.	

RECOMMENDATION 5: LINOLEIC AND α-LINOLENIC ACID (Section 6.2.3)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG chair with the exception of the upper limit for linoleic acid which ISDI considers should be specified as a GUL not a maximum.
JUSTIFICATION	
ISDI agrees with eWG Chair's recommendation to adopt the compositional requirements for linoleic acid and α-linolenic acid, as well as the ratio, as specified in the Codex Standard for Infant Formula. The proposed levels are considered to be sufficient to meet the needs of older infants in combination with complementary feeding. Setting a GUL for linoleic acid in the revised Codex Standard for Follow-up	

Formula similar to that in the Codex Standard for Infant Formula would be appropriate.

RECOMMENDATION 6: DHA, ARA and EPA (Section 6.2.4)	**ISDI COMMENTS**
	ISDI reiterates its position as detailed in CP2 not to have a mandatory link between DHA and ARA, i.e. the position is that the addition of ARA is optional when DHA is added in follow-up formula for older infants. **On footnote 20:** Footnote 20 should modified to capture these points: ***Docosahexaenoic Acid[20)]*** *[20)] If docosahexaenoic acid (22:6 n-3) is added to Follow-up Formula for older infants, the addition of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3) are optional. If arachidonic acid were to be added then its content should reach at least the same concentration as DHA. If eicosapentaenoic acid were to be added its content should not exceed the content of docosahexaenoic acid.*

JUSTIFICATION

ISDI acknowledges the excellent overview prepared by the eWG Chair regarding the compositional recommendations under section 6.2.4. for long-chain polyunsaturated fatty acids in follow-up formulas for older infants.

The responses to the eWG Chair are in general aligned with the ISDI position set-out in response to the 2nd Consultation paper, reiterated here:

> *"Several expert opinions have concluded that the dietary DHA intake may be low in older infants and that given the nutritional requirements for DHA, its addition to older infants diets/Follow-up Formulas for older infants may/should be recommended (EFSA, 2014; ENA, 2012; Afssa, FAO/WHO, 2009). However, given there is still no general consensus regarding DHA supplementation within the scientific community, ISDI considers that it would be most appropriate to recommend that the addition of DHA to Follow-up Formula for older infants is optional*
>
> *Provisions defined in the Infant Formula Standard should apply as far as needed (see next section).*
>
> *ISDI support the addition of DHA as an optional nutrient, and does not support ARA and EPA as essential addition. The addition of ARA and the EPA has to be optional and not linked to the addition of DHA."*

Based on the above, the eWG recommendation 6 "*that CCNFSDU agree to consider the addition of DHA, ARA and EPA as optional additions to follow-up formula*" is generally aligned with the ISDI position.

However, the eWG proposal under section 7, optional ingredients for older infants (6-12 months), specifies compositional criteria that link the addition of DHA to ARA, similar to the compositional criteria defined for DHA in the Codex Standard for Infant Formula (Codex STAN 72-1981).

ISDI considers that there is scientific consensus to support the addition of DHA to follow-up formula for older infants. However, ISDI considers that on the contrary there is at neither sufficient evidence nor scientific consensus to define strict criteria for the levels of ARA, when DHA is added (ENA, 2012; EFSA, 2013; EFSA, 2014).

Hence, ISDI considers that when DHA is added, the criteria for optional addition of ARA should be less prescriptive as for EPA. Therefore ISDI proposes modifying the footnote associated with the optional addition of DHA in line with our position and scientific consensus as follows:

Docosahexaenoic Acid[20)]

[20)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula for older infants, the addition of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3) are optional. If arachidonic acid were to be added then its content should reach at least the same concentration as DHA. If eicosapentaenoic acid were to be added its content should not exceed the content of docosahexaenoic acid.

References

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

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

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

RECOMMENDATION 7: CARBOHYDRATES (Section 6.2.5)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair.

RECOMMENDATION 8: VITAMIN A (Section 6.3.1)	**ISDI COMMENTS**
	ISDI does not support the recommendation of the eWG Chair for a maximum vitamin A level that is aligned with the existing Codex Standard on Infant Formula. ISDI supports the retention of the existing maximum for vitamin A at 225 µg RE/100 kcal provided for in the Codex Standard on Follow-up Formula.

JUSTIFICATION

- The range proposed by the eWG is lower as compared to the current range in the Codex Standard for Follow-up Formula. This will generate technological feasibility challenges for vitamin A due to nutrient stability and analytical variability as previously reported by McLean *et al.* (2010); Vitamin A stability is reported to be ≥ 25% and vitamin A analysis subject to significant intra- and inter-laboratory variability (Maclean *et al.*, 2010).
- There is no evidence of safety of use at the existing maximum of 225 µg RE/100 kcal.
- Therefore ISDI recommends maintaining a current range of 75-225 µg RE/100 kcal.

References

MacLean Jr W, Van Dael P, Clemens R, *et al.* (2010) Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. *Journal of Food Composition and Analysis*, 23:44–53.

RECOMMENDATION 9: VITAMIN D (Section 6.3.2)	**ISDI COMMENTS**
	ISDI does not support the recommendation of the eWG Chair and maintains its position for a minimum at 2.0 µg/100 kcal and a maximum at 4.5 µg/100 kcal. However, in the context of moving the revision of the Codex Standard forward, ISDI could accept the proposal of the eWG Chair for a minimum at 1.0 µg/100 kcal, but still advocates for maximum of 4.5 µg/100 kcal.

JUSTIFICATION

ISDI elaborated its position regarding the levels for vitamin D in CP2 and wants to reiterate our support for this position.

However, in an effort to move the revision forward, ISDI could support retention of the minimum vitamin D level of 1 µg/100 kcal consistent with the Codex Standard for Follow-up Formula. On the other hand ISDI

retains its position that the maximum should be increased to 4.5 µg vitamin D/100 kcal to effectively manage sub-optimal vitamin D status in some regions (Saraf *et al.*, 2015; Koletzko *et al.*, 2013).

ISDI wants to emphasize that this higher level is safe for use as there is no risk of exceeding the tolerable upper level revised in 2010 by the American Institute of Medicine (IOM): 40 µg/day for infants aged 6-12 months. A mean consumption of 450 ml of follow-up formula (cited in CX/NFSDU 14/36/7) containing 4.5 µg/100 kcal would approximately bring 13.6 µg/day of vitamin D (assuming an energy density of 67 kcal/100 ml), which is far below the tolerable upper level.

References

Saraf R, Morton SM, Camargo CA Jr *et al.* (2015) Global summary of maternal and newborn of vitamin D status - a systematic review: *Maternal & Child Nutrition* Sep 15. doi: 10.1111/mcn.12210. [Epub ahead of print]

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

Institute of Medicine (2010) Dietary Reference Intakes for Calcium and Vitamin D.

RECOMMENDATION 10: VITAMIN B6 (Section 6.3.3)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair for a minimum at 35 µg /100 kcal, a GUL at 175 µg /100 kcal and the deletion of footnote.
JUSTIFICATION	
As the proposed protein levels are being lowered compared to those found in the current Codex Standard for Follow-up Formula (minimum possibly up to 1.65 as compared to 3.0 g/100 kcal), the minimum level established based on this footnote would be lowered to 24.8 µg/100 kcal. As a consequence the footnote should therefore be deleted as it would not enable compatibility with the minimum vitamin B_6 level of 35 µg/100 kcal.	

RECOMMENDATION 11: FOLIC ACID (Section 6.3.4)	**ISDI COMMENTS**
	ISDI supports the eWG Chair's recommendation.

RECOMMENDATION 12: IRON (Section 6.4.1)	**ISDI COMMENTS**
	ISDI does not agree with the recommendation by the eWG Chair and maintains its previous position for the upper limit applied to be a GUL rather than a maximum. However, in the context of moving the revision of the Codex Standard forward, ISDI could accept the proposed limits, including the specification of upper levels.
JUSTIFICATION	
Iron deficiency is the most common micronutrient deficiency worldwide (WHO/UNICEF/UNU, 2015; Hernell, 2012). Furthermore, older infants and young children are especially at risk of inadequate intakes of iron (WHO/FAO, 2006). This is primarily because: 1) Daily iron requirements per kg bodyweight are higher during late infancy and early childhood than during any other period of life (Domellof, 2011); 2) The immaturity of the gastrointestinal tract in older infants may negatively influence iron absorption (Krebs, 2001) and; 3) Many older infants do not consume large quantities of iron-rich foods such as red meat and green leafy	

vegetables.

Besides a high risk of inadequate intakes (EFSA, 2013), older infants and young children are also particularly vulnerable to the consequences of iron deficiency because of their rapidly developing brain. From 6 months onwards till one year of life, iron requirements increase considerably, (Hernell, 2001) therefore it seems scientifically relevant to propose a higher level of iron fortification as compared to Codex Standard for Infant Formula.

ISDI therefore supports the recommendation of the eWG Chair to set a minimum level of 1 mg/100 kcal.

Given expert recommendations regarding providing upper iron levels (Dewey, 2002; Lozoff, 2012) ISDI can support the recommendation of the eWG Chair for a maximum level of iron in follow-up formula for older infants.

References

WHO/UNICEF/UNU (2001) Iron deficiency anaemia: Assessment, prevention and control. A guide for programme managers. Geneva, Switzerland. p. 1-132.

Hernell O, Fewtrell MS, Georgieff MK, *et al.* (2015) Summary of current recommendations on iron provision and monitoring of iron status for breastfed and formula-fed infants in resource-rich and resource-constrained countries. *Journal of Pediatrics*, 167:S40-7

WHO/FAO (2006) Guidelines on food fortification with micronutrients. Allen L, *et al.* Editors. Geneva, Switzerland.

Domellof M (2011) Iron requirements in infancy*. Annals of Nutrition and Metabolism*, 59:59-63.

Krebs NF (2001) Bioavailability of dietary supplements and impact of physiologic state: infants, children and adolescents. *Journal of Nutrition*, 131:1351S-4S.

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

Dewey KG, Domellof M, Cohen RJ, *et al.* (2002) Iron supplementation affects growth and morbidity of breast-fed infants: Results of a randomized trial in Sweden and Honduras. *Journal of Nutrition*, 132:3249-3255.

Lozoff B, Castillo M, Clark KM, *et al.* (2012) Iron-fortified vs low-iron infant formula: Developmental outcome at 10 years. *Archives of Pediatric & Adolescent Medicine*, 166:208-215.

RECOMMENDATION 13: CALCIUM & PHOSPHORUS **(Section 6.4.2)**	**ISDI COMMENTS**
	ISDI's position is not in agreement with the proposal by the eWG Chair. ISDI maintains its previous position proposing minimum levels for calcium and phosphorus at 90 mg/100 kcal and 60 mg/100 kcal, respectively. However, in the context of moving the revision of the Codex Standard for Follow-up Formula forward, ISDI could accept the proposal of the eWG Chair for minimum levels for calcium and phosphorus at 50 mg/100 kcal and 25 mg/100 kcal, respectively. With respect to GULs, ISDI maintains its previous position that only a GUL for calcium is required when setting calcium to phosphorus ratio. Hence, ISDI proposes a GUL is set for calcium only, and that this should be set at a level of 200mg/100kcal. Phosphorus levels will be determined by the calcium to phosphorus ratio. ISDI realizes that its proposal may require further discussion at the Physical WG meeting at the CCNFSDU meeting in November.
JUSTIFICATION	
Calcium the GUL proposed of 180mg/100 kcal by the eWG Chair is lower than the minimum calcium level proposed by an independent expert group of 200mg/100 kcal for the 12-26 month age group (Suthutvoravut *et al*., 2015). Therefore ISDI recommends the GUL for calcium is considered in the context	

of this proposed minimum.

Phosphorus

ISDI maintains its position for a minimum of 60 mg/100 kcal but can accept minimum proposed by the eWG Chairs of 25mg/100 kcal in the interests of progressing. However ISDI does not support the eWG Chair's suggested GUL for phosphorous (or any maximum or GUL for phosphorous) on the basis that the calcium:phosphorous ratio is the more significant aspect for phosphorous.

Similar to the comments above on calcium, ISDI recommends further consideration given to the limits applied to phosphorus in the further discussion of the limits for the 12-36 month age range.

References

Suthutvoravut U, Olayele Abiodun P, Chomtho S, *et al*. (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. *Annals of Nutrition and Metabolism*, 67:119–132

RECOMMENDATION 14: MANGANESE (Section 6.4.3)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair.
JUSTIFICATION	
Please also refer to recommendation 2.	

RECOMMENDATION 15: IODINE (Section 6.4.4)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair
JUSTIFICATION	
Please also refer to recommendation 2.	

RECOMMENDATION 16: SELENIUM (Section 6.4.5)	**ISDI COMMENTS**
	ISDI does not support the recommendation of the eWG Chair and maintains its position for a minimum at 1.0 µg/100 kcal. However, in the context of moving the revision of the Codex Standard forward, ISDI could accept the proposal of the eWG Chair for a minimum at 2.0 µg/100 kcal.

RECOMMENDATION 17: COPPER (Section 6.4.6)	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair, for the minimum, but maintains its position for a GUL at 250 µg/100 kcal.
JUSTIFICATION	
A GUL of 250 µg/100 kcal is advised by the International Expert Group coordinated by the Early Nutrition Academy**.** There is no safety concern raised. ***References*** Koletzko B, Bhutta ZA, Cai W, *et al.* (2013) Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 62:44–54.	

RECOMMENDATION 18: ZINC (Section 6.4.7)	**ISDI COMMENTS**

	ISDI supports the recommendation of the eWG Chair on the minimum. ISDI maintains its previous position regarding the GUL to be set at 1.5 mg/100 kcal.
JUSTIFICATION	
ISDI notes that the proposed reduced zinc range of 0.5 – 1.0 mg/100 kcal, as compared to the existing range of 0.5 – 1.5 mg/100 kcal established in the Codex Standard for Infant Formula, may be challenging for manufacturers due to technological aspects. Therefore ISDI recommends adopting a GUL of 1.5 mg/100kcal as recommended by the International Expert Group (2012) and is aligned with the existing Codex Standard for Infant Formula.	

OTHER SUBSTANCES: CHOLINE, MYO-INOSITOL & L-CARNITINE (Section 6.5)

RECOMMENDATIONS 19,20,21: CHOLINE, MYO INOSITO,L CARNITINE **(Section 6.5)**	**ISDI COMMENTS**
	ISDI supports the recommendation of the eWG Chair.
	ISDI supports the recommendation of the eWG Chair.
	L-Carnitine ISDI recommends that if L-Carnitine is added, it is aligned with the Codex Standard on Infant Formula L-carnitine Unit Minimum Maximum GUL mg / 100 kcal 1.2- - - mg / 100 kJ 0.3 -
JUSTIFICATION	
Choline, myo-inositol and L-carnitine are provided via the diet, they do not require mandatory addition to follow-up formula for older infants. According to EFSA, their intake from complementary food is sufficient in older infants (EFSA 2014). Hence their addition to follow-up formula should be optional contrary to the Codex Standard for Infant Formula. ***References*** EFSA (2014) Scientific opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*, 12:3760.	

OPTIONAL INGREDIENTS FOR OLDER INFANTS (6-12 MONTHS) (Section 7)

CHAIR PROPOSAL – OPTIONAL INGREDIENTS (Section 3.3.2)	**ISDI COMMENTS**
	ISDI proposes the following wording: **3.3.2.1** "In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [or substances] may be added **to ensure that** the product **is suitable to form part of a** progressively diversified diet~~. OR [the complementary diet] intended for use [from 6th months on] OR [from the age of 6 months/from 6 months of age] OR [by older infants~~]." **3.3.2.2** "The suitability for the particular nutritional uses in products for older infants ~~and the safety of these [ingredients and] substances~~ shall be scientifically demonstrated **as part of a complementary feeding diet**; **the safety of these ingredients/ substances shall be scientifically demonstrated at the level of use**."

	3.3.2.3 ISDI strongly supports the inclusion of the statement that the list of optional ingredients included is not an exhaustive list. "**The product shall contain a significant amount of these ingredient/ substances to achieve the intended nutritional/physiological/functional effect , taken into account levels of follow-up formula in complementary feeding based on the normal intake of older infants as part of a classical feeding diet**."
	ISDI proposed the following wording on footnote 20: "*If docosahexaenoic acid (22:6 n-3) is added to follow-up formula* ***for older infants****,* ***the addition of*** *arachidonic acid (20:4 n-6)* ***and eicosapentaenoic acid (20:5 n-3) are optional. If arachidonic acid were to be added then its content should reach at least the same concentration as DHA. If eicosapentaenoic acid were to be added its content should not exceed the content of docosahexaenoic acid."*** **L-Carnitine** ISDI recommends that if L-Carnitine is added, it is aligned with the Codex Standard on Infant Formula. L-carnitine Unit Minimum Maximum GUL mg / 100 kcal 1.2 - - mg / 100 kJ 0.3 - -
JUSTIFICATION	
ISDI supports • The permission of "optional ingredients" when their safety and suitability for the particular nutritional use in products for older infants has been evaluated and established by generally accepted scientific evidence. • That guidance from recognized scientific expert groups should be taken into consideration when ingredients are introduced into follow-up formula for older infants. • The alignment of the "Optional ingredient" clause of the revised Standard with Clauses 3.2.1-3.2.3 of the Codex Standard of Infant Formula, with appropriate amendments as suggested above to take the specificity of the older infant target population into account. • That optional ingredients need to provide a beneficial effect as demonstrated by generally accepted scientific data and can, but not need to be present in breast milk. • Scientific evaluation based on the proposed established principles conducted in other countries or related prescriptive regulation should be recognized to facilitate lead times in bringing innovative products to market and reduce regulatory burden. ISDI shares the view of the eWG Chair that the list of optional ingredients is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added.	

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12 – 36 MONTHS) (Section 8)

CHAIR PROPOSAL (Section 8.2)

The composition of follow-up formula for young children (12-36 months) shall be presented as a narrow list of mandatory nutrients with the option of national authorities requiring additional mandatory nutrients based on the nutritional needs of their population.

ISDI COMMENTS

ISDI considers that key principles for compositional requirements are to include flexibility, less prescription, consistency, key nutrients and nutritional integrity.

ISDI considers that the compositional requirements need to be aligned with the Codex principles of developing a global standard facilitating trade of follow-up formula as defined in Section 2 of the draft revised Codex Standard for Follow-up Formula.

Consequently ISDI considers that those key principles can be achieved by defining mandatory and optional compositional criteria.

ISDI supports the principle of nutrient addition under national discretion as long as it remains exceptional to address the unique nutritional needs of specific populations and maintains the principle of Codex Alimentarius.

Lastly, ISDI does not see any justification for introducing a new category for voluntary compositional criteria.

Justification

ISDI supports the approach taken by the eWG Chair with regards to the compositional requirements for follow-up formula for young children (12 – 36 month). ISDI agrees the key principles for compositional requirements are to include the following themes: flexibility, less prescription, consistency, key nutrients and nutritional integrity. ISDI also considers that the compositional requirements need to be aligned with the Codex principles of developing a global standard facilitating trade of follow-up formula as defined in Section 2 of the draft revised Codex Standard for Follow-up Formula.

ISDI recognizes that the eWG aims for flexibility by defining a narrow list of mandatory nutrient requirements, a list of discretionary voluntary and optional ingredients and additional national discretion for further nutrient additions. ISDI does not support this approach offers to countries the opportunity to create variations for the compositional criteria and thus will not enable to develop a global harmonized standard, as stated a core principle of Codex Alimentarius. Too many variations of follow-up formula may result in unnecessary variations in nutritional criteria and product quality, which will increase confusion among consumers. Finally this is not consistent with the aim of the Codex principles of developing harmonized standards to facilitate trade.

ISDI considers that flexibility, global harmonization and consistency of follow-up formula can be achieved by defining mandatory and optional compositional criteria. The mandatory compositional criteria refer to essential and/or conditionally essential nutrients for which insufficient dietary intake is generally reported in young children (e.g. iron). The optional compositional criteria refer to nutrients that are either essential or conditionally essential with reported adequate dietary intakes in young children or to other nutrients for which functional benefits have been demonstrated.

ISDI supports the principle of nutrient addition under national discretion as long as it remains exceptional to address the nutritional needs of their specific population and maintains the principle of Codex Alimentarius.

Finally ISDI does not see any justification for introducing a new category for voluntary compositional criteria.

MANDATORY ADDITIONS (Section 8.2)

ISDI supports establishing mandatory compositional criteria for the following nutrients for follow-up formula for young children:

- Protein
- Fat – consider the fatty acid profile, including parameters for ALA and LA and maximum limits for trans fatty acids and saturated fatty acids
- Carbohydrate – based on residual energy after fat and protein contribution has been calculated. Consider including a limit for the addition of sugar.
- Iron
- Calcium ; **Phosphorus**
- Vitamin A
- **Vitamin B_{12}**
- **Vitamin D**
- **Vitamin C**
- **Zinc**
- **Iodine**

- **Folic Acid**
- **Sodium**

Justification

ISDI considers that that flexibility, global harmonization and consistency of follow-up formula can be achieved by defining mandatory compositional criteria for essential and/or conditionally essential nutrients that are critical for growth and development and for which insufficient dietary intake is generally reported in young children. The nutrients listed in ISDI's comments above (with the exception of sodium) meet these criteria and have been frequently reported to be limited in the diets of young children, even if these differed regionally as acknowledged by CCNFSDU (see section 8), and some of them are sourced by cow milk. In the case of sodium ISDI proposes a maximum level is specified.

VOLUNTARY ADDITIONS (Section 8.2)

ISDI does not support the recommendation of the eWG Chair regarding voluntary addition of ingredients as highlighted above. With respect to vitamins and minerals, not listed in the mandatory compositional criteria, these must satisfy the compositional criteria for optional nutrients. The compositional criteria for optional nutrients should be scientifically defined. The recommendation by the eWG Chair to refer the compositional requirements defined for follow-up formula for older infants can be considered as a starting point, although ISDI considers this is not appropriate for most optional nutrients.

Justification

Compositional requirements for follow-up formula for older infants are not tailored for young children.

Considering general consumption data (2-3 servings/day or ~300-500 kcal/day) dietary nutrient intakes based on compositional criteria for follow-up formula for older infants would result in :

- Potentially exceeding nutrient intakes as compared to nutrient requirements for young children (12-36 months) for vitamin A, zinc, copper, and iodine;
- Potentially deficient nutrient intakes as compared to nutrient requirements for young children (12-36 months) for vitamin D, calcium, vitamin E, folic acid, manganese, vitamin B6, niacin and selenium.

Assessment of adequacy of these compositional criteria will of course be largely dependent of the dietary characteristics and practices. Hence more in-depth assessment may be needed in order to establish appropriate compositional criteria for optional nutrients.

A risk of insufficient intake has been identified in young children, and while this is variable among regions, there appears to be a trend toward inadequate intake of alpha-linoleic acid, iron, zinc, calcium, iodine, vitamin A, vitamin D, vitamin C, and vitamin E (Ghisolfi *et al.,* 2013; Walton and Flynn, 2013).

Therefore as mentioned above, ISDI considers that a more in-depth assessment of mandatory and optional compositional criteria is conducted to define the most safe and nutritious way in defining adequate compositional criteria for follow-up formula for young children.

References

Institute of Medicine (2005) Dietary Reference intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, D.C.: National Academies Press.

Ghisolfi J, Fantino M, Turck D, *et al.* (2013) Nutrient intakes of children aged 1-2 years as a function of milk consumption, cows' milk or growing-up milk. *Public Health Nutrition*, 16:524-34.

Walton J and Flynn A (2013) Nutritional adequacy of diets containing growing up milks or in fortified cow's milk in Irish Children (aged 12 – 24 months). *Food and Nutrtion Research* DOI:3402/fnr.v57i0.21836.

OPTIONAL INGREDIENTS (Section 8.2)

ISDI supports the recommendation of the eWG Chair for optional nutrients or ingredients along the principles highlighted above. In summary optional nutrients based on generally accepted scientific data.

The criteria for the addition of optional ingredients used in follow-up formula for young children can be based on the same principles defined for follow-up formula for older infants.

NATIONAL AUTHORITY DISCRETION (Section 8.2)

ISDI supports the principle of nutrient addition under national discretion as long as it remains exceptional to address the nutritional needs of their specific population and maintains the principle of Codex Alimentarius.

NEXT STEPS (Section 9)

REPORT

ISDI agrees with Chair's proposals.

Comment

With respect to the essential compositional criteria for follow-up formula for yong children, ISDI supports the concept proposal of the eWG Chair to elaborate on these in-depth. ISDI considers that the principles outlined in our comments should be taken into consideration in establishing the revised Codex Standard for follow-up formula. ISDI considers that these principles will support high quality, safe and nutritious follow-up formulae for young children aligned with the core principles of Codex Alimentarius regarding global harmonized standards.