CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CX/NFSDU 16/38/6-Add.1**

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

Thirty-eighth Session

Hamburg, Germany

5 – 9 December 2016

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

Comments of Argentina, Brazil, Canada, Colombia, Costa Rica, Cuba, Nepal, New Zealand, Norway, Philippines, United States of America, AOCS, CEFS, ELC, ENSA, ENSA/EUVEPRO, HKI, IBFAN, IDF and ISDI

ARGENTINA

Essential composition of follow-up formula for older infants (over 6 months)

- **Recommendation 1**. Proteins

Argentina agrees with the minimum value for proteins; eliminate the square brackets in Note 2 and Note 3; it agrees with Note 4 and Note 6, which state that follow-up formula based on hydrolysed proteins should be evaluated clinically.

- **Recommendation 2**. Vitamin K

Argentina agrees with the proposal that has been made.

- **Recommendation 3**. Vitamin C

Argentina agrees with the proposal that has been made.

- **Recommendation 4**. Zinc

Argentina agrees with the proposal that has been made.

- **Recommendation 5**. DHA

Argentina agrees with the footnote.

- **Recommendation 6**. Lactic acid producing cultures.

Argentina agrees with the proposal and it believes that the addition of lactic acid producing cultures for nutritional purposes is only appropriate if the benefits have been demonstrated with recognised scientific evidence.

Essential composition of follow-up formula for young children (12-36 months)

- **Recommendation 7**. Division of the standard into Section A (older infants) and Section B (young children)

Argentina agrees with this proposal

- **Recommendation 8**. Additional options:

It agrees with Option 1. If there is a health-related need (at the regional/country level) to add other nutrients and/or ingredients not included in the composition (core composition), an evaluation should be conducted in each instance on the basis of the scientific evidence that supports such addition.

- **Recommendation 9**. Requirements concerning energy content

Argentina agrees with the proposal that has been made.

- **Recommendation 10**. Minimum values for carbohydrates. Proteins

Argentina agrees with the proposed values for carbohydrates and proteins and the footnotes on proteins.

- **Recommendation 13**. Fat and hydrogenated oils.

Argentina agrees with the proposal.

- **Recommendation 14**. Type of carbohydrates

Argentina agrees with this proposal for carbohydrates.

- **Recommendation 15**. Iron and vitamin C

Argentina agrees with the proposal.

- **Recommendation 16 (2).** Zinc

Argentina agrees with the proposal.

- **Recommendation 20**. Divide the standard into two parts, Section A and Section B

Argentina agrees with the proposal.

BRAZIL

Specific Comments

Recommendation 1

Brazil supports the recommendation of adopting the minimum protein value of 1.8g/100kcal and the maximum protein value of 3.0g/100kcal. The minimum protein value of 1.8g/100kcal is nutritionally adequate to support growth and development of older infants and it is in line with the Codex Standard for Infant Formula (CODEX STAN 72-1981). 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 states that 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 also supports its previous position. 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, we understand that it could be aligned with the requirements of CODEX STAN 72-1981, i.e., 3.0g/100kcal.

Footnote 2

Brazil supports the recommendation of deleting the square brackets. However, we note that the conversion factor for soy products in IF Codex Stan and Follow-up formula Stan should be reviewed when the outcomes of the FAO/WHO expert panel are available.

Footnote 3

Brazil supports footnote 3. The reference protein for follow-up formula should be the amino acid composition of breast milk as defined in Annex I of the Codex Standard for Infant Formula.

Footnotes 4 and 5

Brazil supports footnotes 4 and 5.

Footnote 6

Brazil is still of the opinion that there is no reason to use hydrolysed protein in follow-up formula intended for healthy older infants. 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. , 2010; BERG, A et al., 2013; IEG, 2013 ; EFSA, 2014; BOYLE et al., 2016). Hence, there would not be a justification for using hydrolysed protein in follow-up formula intended for healthy older infants.

Nevertheless, considering the recommendation of the eWG to retain the footnote 6, Brazil thinks that all formulas based on hydrolysed protein should be clinically evaluated, because the safety and suitability of infant formula containing protein hydrolysates have not been fully demonstrated. According Mennella

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

et al, 2016[2], little research has focused on infant developmental effects, other than growth, of formulas that differ substantially in the form of protein and data suggest that the form of protein in infant formula may impact cognitive development.

Therefore Brazil proposes that footnote 6 should read:

All formulas based on hydrolyzed protein should be clinically evaluated.

We note that depending on the decision of the Committee, the IF Standard (Codex Stan 72) should be amended accordingly.

Recommendation 2

Brazil still considers that the minimum level of vitamin K could be lowered to 1µg/100 kcal considering that the concerns regarding the association between low vitamin K levels and haemorrhagic problems are referenced only to neonates.

Moreover, assuming an average energy intake of an older infant of 500 mL/day, the minimum limit of 1µg/100 kcal would meet the requirements of this age group, considering the AI established of 2.5 µg/day (IOM, 2001).

Nevertheless, as a compromise to reach a consensus and to align with the IF Codex Standard 72, Brazil could accept the minimum value of 4µg/100 kcal.

Recommendation 3

Brazil supports the recommendation of adopting a minimum vitamin C level of 10 mg/100 kcal.

Based on the AI of 50mg/day (IOM, 2000), vitamin C intake from human milk with a vitamin C concentration of about 45 mg/L at 9 months (the midpoint of this age group) of lactation would be approximately 27 mg/day. Adding the intake from milk (27 mg/day) and solid foods (22 mg/day), the total AI for vitamin C is rounded to 50 mg/day.

Thus, assuming an average energy intake of an older infant of 600 mL/day and considering that the formula should provide nearly 27mg/day, the minimum limit of 4mg/100kcal would provide 16mg of vitamin C/day which does not cover these needs. It is also important to consider that the daily intake of 750mL of formula (~500kcal/day) is not usual in this age group. In general, the intake is around 600mL/day.

Moreover, with the minimum value of 10mg/100kcal, the AI of 50mg/day would be met regardless the intake of solids food from complementary feeding and would not pose risk to children.

Recommendation 4

With regard to the GUL for zinc, Brazil understands that the GUL of 1.0 mg/100 kcal would be more appropriate.

The amount of 1.5mg/100kcal extrapolates the tolerable upper level of 5mg established by IOM (2004) for older infants, assuming an intake of 500 kcal/day of formula.

Nevertheless, the eWG acknowledge that although intakes could lead to exceeding the UL established by some recognised authorative scientific bodies that any risk associated with this was deemed negligible. Additionally, the UL or NOAEL for zinc intake defined by WHO, IOM and IZiNCG varies: 13mg/d (7-12 months), 5mg/d (7-12 months), 6mg/d (6 – 11 months), respectively (Gibson et al, 2016[3]).

Hence, as a compromise to reach a consensus and to align with the Codex Standard for Infant Formula, Brazil could accept the GUL value of 1.5 mg/100 kcal.

Recommendation 5

Brazil supports the recommendation. We understand that there is no need to specify a minimum level for DHA, considering the sources from complementary feeding. Brazil agrees that the decision should be left to the competent national and/or regional authorities.

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

[3] Gibson RS, King JC, Lowe N. A review of dietary zinc recommendations. Food Nutr Bull. Jun, 2016.

Recommendation 6

Based on the available scientific literature, there are still doubts regarding the safety and benefits of adding microorganisms in formulas. Thus, there is no justification for the addition of these microorganisms in formulas.

Brazil is of the opinion that the safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence. It should also be considered the safe dilution temperature for preparation of powdered infant formulas recommended by FAO/WHO (2007) and by Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (2008). Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria, when added for particularly nutritional purposes. Given that, if the Committee decides to retain this provision, Brazil agrees with the text proposed for section 1.3.2.5.

With regard to the section 1.3.2.4, we would like to point out issues raised in the 2nd CP of the eWG. Some studies mentioned in the 2nd CP indicate that any benefits of these fermented products are attributed to the remaining bacterial components, such as cell membrane, or bacterial DNA and/or the effects of bacterial metabolites (lactic acid and other organic acids). It is also suggested that fermented formula have been used in preventing and treating acute diarrhoea and digestive symptoms. However, the authors concluded that fermented formulas do not confer additional benefits than those provided by standard infant formula (Szajewska and colleagues, 2015[4]).

Hence, Brazil considers that the technological use of L(+) lactic producing cultures for the purpose of producing acidified follow-up formula for older infants should be further discussed by the Committee as the studies suggest that these bacteria have been added for other purposes. Given that, Brazil is of the opinion that the safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for the purpose of producing acidified follow-up formula for older infants shall also be demonstrated by generally accepted scientific evidence. Thus, if the Committee decides to retain section 1.3.2.4, Brazil suggests including the need of safety and suitability assessment:

1.3.2.4 [Only L(+) lactic producing cultures may be used **for the purpose of producing acidified follow-up formula for older infants. <u>The safety and suitability of the addition shall be demonstrated by generally accepted scientific evidence</u>**.]

Recommendation 7

Brazil supports recommendation 7.

Recommendation 8

Brazil agrees with the proposed approach for mandatory (core) composition of follow-up formula for young children. The nutrients included in the mandatory composition should meet one of the following three principles:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale; and/or
2. contribution of adequate amounts of key nutrients from cows' milk, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety.

For national authorities requiring the mandatory addition of other essential nutrients for their specific population, we agree that these nutrients should be chosen from the essential composition of follow-up formula for older infants. Nevertheless, for consistency with the approach proposed to set the levels of other nutrients included in the mandatory composition, we consider that the levels of other essential nutrients must be determined based on the same pragmatic approach i.e. which enables the nutrient composition of both follow-up formula for older infants and cows' milk. As presented in CX/NFSDU 16/38/6, for those nutrients that are not present or are present at very low levels in cows' milk the minimum and maximum/GUL levels of follow-up formula for older infants are recommended for follow-up formula for young children, and for those nutrients that are naturally present in cows' milk the minimum could be set at the minimum stipulated for follow-up formula for older infants, while the

[4] Szajewska H, Skórka A, Piescik-Lech M. Fermented infant formulas without live bacteria: A systematic review. *Eur J Pediatr*. 2015;174(11):1413-1420. Accessed 12 June 2016. doi: 10.1007/s00431-015-2629-y.

maximum/GUL could be set at the highest of two values: either the maximum/GUL permitted for follow-up formula for older infants, or the level in cows' milk to ensure flexibility.

Thus, Brazil suggests the following text for consideration by the Committee:

For national authorities requiring the mandatory addition of other essential nutrients for their specific population, these nutrients should be chosen from the essential composition of follow-up formula for older infants. The nutrient levels must be:

- based on the nutrient composition of both follow-up formula for older infants and cows' milk; or
- amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants or from the levels of cows' milk.

With regard to optional addition, Brazil is in favour of option 1. However, we would like to suggest amending the 4th bullet based on the same reasons mentioned for determining the levels of mandatory addition of other essential nutrients:

- [Additional nutrients may also be added to follow-up formula for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are:
  - based on the nutrient composition of both follow-up formula for older infants and cows' milk; or
  - amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants or from the levels of cows' milk.

Recommendation 9

Brazil supports the requirements for energy density recommended by the Chairs, i.e., 60 – 70 kcal/100mL based on the comments presented by some eWG members that reduced fat cows' milk is not recommended for children aged 12-24 months in most national dietary guidelines as it could compromise intakes of energy and essential fatty acids necessary for growth and development.

We are not in favour of establishing a different minimum value for young children aged 24 to 36 months as the product is intended to young children in general which includes the range of 1 to 3 years of age. It is also important to take into account that the Committee has already agreed that there should be a point of differentiation at the age of 12 months. A distinct minimum value for young children aged 24 to 36 months can lead to confusion with regard to the indication of the product.

Recommendation 10

Brazil supports the recommendation that the level of available carbohydrates should not exceed 12 g per 100 kcal (2.9 mg per 100 kJ). We would like to ask for clarification about the use of both terms total and available carbohydrate. If the term available carbohydrate is used, it is necessary to clarify what constitutes available carbohydrates.

Brazil considers important setting minimum and maximum limits for protein taking into account the 3rd principle, i.e., to ensure the nutritional quality and integrity of product. In relation to the minimum limit, we agree with the value of 1.8g/100kcal. We also think that the maximum limit should also be determined considering the risk of obesity associated with excessive intakes of protein. Hence, Brazil suggests the maximum level of 3.0g/100kcal based on the AMDR of 12% E for further discussion by the Committee.

Brazil agrees with the minimum level for total fats of 4.0 g/100 kcal.

Recommendation 11

Brazil will wait the discussion to provide comments.

Recommendation 12

Brazil is of the opinion that the levels for α-linolenic acid should be established for follow-up formula for young children. With regard to the level, we support the minimum level of 50 mg per 100 kcal for α-linolenic acid.

We also suggest including a mandatory requirement for linoleic acid. The levels could be aligned with the requirements for follow-up formula for older infants (minimum: 300 mg/100 kcal (72 mg/100 kJ); GUL 1400 mg/100 kcal (335 mg/100 kJ)).

In our opinion, it is also important setting the ratio linoleic acid/ α-Linolenic (minimum of 5:1 and a maximum of 15:1) as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG.

Recommendation 13

Brazil supports recommendation 13.

Recommendation 14

Brazil agrees with recommendation 14.

In relation to the text proposed, we would like to suggest the following amendment for clarification regarding the need of limiting the addition of sucrose and/or fructose:

Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. **Sugars,** other than lactose but **including** sucrose and/or fructose, should not be added, unless needed as a carbohydrate source, and provided that does ~~Sugars, other than lactose, should~~ not exceed 10% of available carbohydrate].

We also support the additional sentence “Lactose should be the preferred carbohydrates in formula based on milk protein [and should provide not less than 50% of total carbohydrates].”

As pointed out in the response of recommendation 10, we would like to ask for clarification about the use of both terms total and available carbohydrate. If the term available carbohydrate is used, it is necessary to clarify what constitutes available carbohydrates.

Recommendation 15

Brazil agrees with recommendation 15.

Recommendation 16

As pointed out in CX/NFSDU 16/38/6, it is recognised that in general follow-up formula for young children is often used as a substitute, alternative or replacement for cows’ milk which is a significant source of calcium, vit. B_2 and vit. B_{12} in the diet. Also, cows’ milk provides over 70% of a young children’s requirement of these nutrients in a 300 mL serve.

Calcium

Hence, Brazil is of the opinion that the product should provide at least 50% of INL_{98} of calcium (500mg/dia; WHO/FAO) in 300mL per day which represents a minimum value of nearly 140mg/100kcal.

However, we acknowledge that the minimum and GUL values for calcium are related with the protein content of the product. Thus, the technological feasibility should be taken into account.

Brazil is of the opinion that the ratio for calcium-to-phosphorous established in the Codex Standard for Infant Formula should be included in order to assure a better absorption efficiency.

Vit. B_2

In line with the rational adopted to derive the suggested minimum value of 140mg/100kcal for calcium, Brazil also understands that the product should provide at least 50% of INL_{98} of vit. B_2 (500µg/dia; WHO/FAO) in 300mL per day which represents nearly 140µg/100kcal. With regard to the GUL of 500µg/100kcal, Brazil can accept the recommendation to align with the follow up formula for older infants. Nevertheless, we highlight that the upper level range of semi-skimmed cows’ milk is 546 µg/100 kcal (Appendix 1/Table 1 of CX/NFSDU 16/38/6), which can lead to technological problems. Hence, we think that the GUL should be further discussed by the Committee.

Vit. B_{12}

In line with the rational adopted to derive the minimum value for calcium and riboflavin, Brazil also understands that the product should provide at least 50% of INL_{98} of vit. B_{12} (0.9µg/dia; WHO/FAO) which represents 0.25µg/100kcal.

Recommendation 16

Brazil will wait the discussion about the evidence to include zinc as a mandatory nutrient at the pWG and plenary session by the Committee.

If the Committee consider there is sufficient evidence to require the mandatory addition of zinc to follow-up formula for young children, Brazil supports the recommended minimum and GUL values.

Recommendation 17

In Brazil, vitamin A deficiency is found in some regions of the country. According to the Brazil National Demographic and Health Survey of Children and Women (PNDS – 2006[5]), vitamin A deficiency was found in 17.4% of children under 5 years of age and 12.3% of women of childbearing age. In children, the higher prevalence was found in the Northeast (19%) and Southeast (21.6%) regions of the country. In women, the higher prevalence was found in the Southeast (14%), Midwest (12.8%), Northeast (12.1%), North (11.2%) and South (8%) regions of the country.

Moreover, Brazil implemented in 2005 a National Vitamin A Supplementation Program for children aged 6-59 months of age and women.

Thus, Brazil is of the opinion that the addition of vitamin A should not be mandatory. It would be more appropriate for individual national authorities to require the mandatory addition of vitamin A at the national level.

If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin A to follow-up formula for young children, Brazil agrees with the recommended minimum and maximum values.

Recommendation 18

Brazil will wait the discussion about the evidence to include vitamin D as a mandatory nutrient at the pWG and plenary session by the Committee.

If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin D to follow-up formula for young children, Brazil supports the recommended minimum and maximum values.

Recommendation 19

Brazil agrees with recommendation 19.

Recommendation 20

Brazil supports recommendation 20.

Brazil understands that the current labelling provisions for follow-up formula (Sections A and B) should be reviewed in order to align with the current Codex labelling requirements for infant formula (Codex STAN 72 – 1981) and other relevant Codex standards and guidelines, where applicable. It is also important to give full consideration to WHO and WHA guidelines and recommendations, including: International Code of Marketing of Breast-milk Substitutes (1981); The Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001); WHA World Health Assembly Resolution 39.28; WHA 63.23 and WHA 69.9 - 8.5.

Recommendation 21

With regard to the definition proposed for ***[Fortified milk product]*** *OR* ***[Processed milk product for young children]*** *OR* ***[Follow-up formula for young children]***, Brazil would like to suggest the following amendment:

[Fortified milk product] *OR* ***[Processed milk product for young children]*** *OR* ***[Follow-up formula for young children]*** *[means a product intended for use as a liquid part of the progressively diversified diet ~~when nutrient intakes may not be adequate to meet the nutritional requirements~~ of young children.]*

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

With regard to the name of the product for young children, Brazil agrees that it is important to establish two very distinctly different product names to clearly distinguish follow-up formula for older infants from follow-up formula for young children. We also agree that the product for young children should not be considered a 'formula' as this confuses product for young children with formula marketed and suitable for use by infants in the first year of life.

[5] Available at http://dab.saude.gov.br/portaldab/ape_vitamina_a.php.

Brazil understands that the proposed names ***[Fortified milk product]*** *or* ***[Processed milk product for young children]*** should be retained in square brackets for further consideration by the Committee in the next year as the discussion on the Scope and Labelling sections are at an initial stage.

CANADA

GENERAL COMMENTS

We would like to comment on the proposals in Section 4 of the agenda paper, which is about the Framework for the Essential Composition of Follow-up Formula for young children (12 – 36 months).

The framework states that 'The outlined approach was for the requirements of the essential composition of FUF-YC to be based on a narrow set of mandatory requirements, with the option that national authorities may require additional mandatory nutrients based on the nutritional needs of their population'. Then under section 4.3, for optional addition, it is stated that 'In addition to the mandatory (core) composition, further essential nutrients may be added to FUF-YC, either as mandated additions to the (core) composition required by national authorities or as an optional addition by manufacturers, provided such needs are substantiated by scientific evidence'.

We find that the proposals for the nutritional composition of FUF-YC with relatively few mandatory nutrients, as proposed by the Chair in Section 5.1, could result in unbalanced formulations being marketed. While in this framework National Authorities may require that further nutrients be mandated for addition to FUF-YC to meet the specific nutritional needs of their population, and provides for optional ingredients to be added as well, we believe that this approach is becoming quite complicated, and again, could result in important nutrients being omitted from the formulation. It is also not guaranteed that all young children will be consuming sufficient complementary foods, along with the FUF-YC as a replacement for cows' milk, to ensure balanced nutrient intakes.

For this reason, Canada believes that a **less** flexible approach is needed, and that it may be time to consider widening out the list of mandatory nutrients.

We have provided in Section 5 below a revised table for the 'Extensive prescribed mandatory (core) composition', to include both the previously stated global nutrients of concern and the key nutrients in cows' milk. This would be our preferred option, and we believe it would be easier to use in formulating a balanced product.

The role of the product as a cows' milk substitute seems to have been lost, somewhat, perhaps due to concentrating on nutrients of concern on a global scale and having lists for optional addition.

We recommend that more work be carried out to ensure that a nutritionally balanced product would be produced if the resultant revised Codex Stan 156 for nutrient content were followed. Nutrients such as the mineral nutrients calcium, phosphorus and magnesium as well as vitamins such as riboflavin and B12 that are present in cow's milk should all be included, along with the nutrients of global concern.

We also note that it is proposed that mandatory and optional nutrients for FUF-YC can be chosen from the essential compositional requirements for FUF-OI, but again this appears to be a piecemeal approach that could also result in unbalanced nutrient intakes.

In addition, Canada does not agree with using the level of addition of nutrients stipulated in the standard for FUF-OI for FUF-YC, as the nutritional needs of older infants and young children differ. The basis for the level of addition should be based on nutrient recommendations for this age group from Recognised Authoritative Scientific Bodies (RASBs). For nutrient naturally present in cow's milk, the minimum and maximum levels could be based on the range found in cow's milk. As for nutrients not found in cow's milk, the Committee could consider establishing levels based on a percentage of the RDA/AI for that age group. We would prefer to have minimum and maximum levels for all nutrients in the Standard, both mandatory and optional, to ensure appropriate addition.

As young children are encouraged to eat an increasingly varied diet of complementary foods, it is not necessary, or appropriate for these products to have a nutritionally complete formulation (such as that of IF or FUF-OI), but it should allow for adequate nutritional intakes when used in amounts of 300 to 500 ml per day along with the nutrient intakes from complementary foods.

The consequences of not having a balanced marketed product must be avoided. It should be made easy for manufacturers to formulate their products by having a clear list of mandatory and optional nutrients, with minimum and maximum amounts as necessary.

In Canada's opinion, having highly variable products on the market could be more confusing to caregivers than is the case currently for the use of different types of follow up formulas, and would not support trade across jurisdictions.

In Section 7, the definition under Recommendation 21 includes a statement that FUF-YC 'means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children'. Canada proposes that this definition will depend on the final composition determined for the product, and should be deferred until this is decided on.

SPECIFIC COMMENTS:

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

3.2 Protein

Recommendation 1

3.2.1 Protein Minimum

Canada continues to support the minimum protein compositional requirements of the Infant Formula Standard, 1.8 g/100 kcal, which also align with the recommendations of EFSA (2014). There is no scientific evidence or rationale to alter the requirements to those established for infant formula throughout the first year of life and 1.8 g/100 kcal is also safe and nutritionally adequate to support growth and neurodevelopment during this critical period of life. This is an international standard that should cover the requirements in different parts of the world where the protein intakes are low and/or of low nutritional quality.

3.2.2 Protein Maximum

Canada continues to support a maximum protein level of 3 g/100 kcal in alignment with the Codex IF

Standard. Canada would like to reiterate that it would be appropriate to have a cushion, since these are international recommendations that should take into consideration the resource limited settings where the protein intakes and quality from complementary foods may also be limited. Please refer to the evidence reported in the response for the minimum above.

3.2.3 Footnotes 2 and 3

For footnote 2, Canada recommends that FAO and WHO convene an expert panel to review the available literature to assess the scientific basis for nitrogen conversion factors, and in the meantime align with the Codex Infant Formula Standard, which uses N x 6.25.

Canada agrees with the proposed changes to footnote 3, to add the reference to the Codex Standard for Infant Formula (CODEX STAN 72-1981).

However, Canada would like to add that the quality of proteins used in the formulas, particularly for the plant source of proteins, should be taken into consideration. For example, soy protein isolates (SPIs) prepared by different manufacturers or through different processes can be very different in their content of active protease inhibitors, which results in different protein bioavailability.

Although it is mentioned that "an available quantity of each essential and semi-essential amino acid…" in this footnote, it is important to note the fact that at least 10% of the active protease (trypsin and chemotrypsin) inhibitors remain in the properly processed soy protein isolate since complete inactivation of these anti-nutritional factors need extensive heating, which will result in reduced absorption of certain amino acids such as lysine and arginine and lowered protein quality. Furthermore, the maximum levels for these protease inhibitors have not been established and their actual content in soy products are not required to be provided.

3.2.4 Requirements for clinical evaluation: Footnote 6

Canada suggests that any hydrolysed formula should be clinically tested for growth, tolerance and adverse events, but in young infants, not older infants consuming complementary foods.

Canada would like to propose the following wording:

[(6) **Follow-up formulas based on non-hydrolysed (intact) protein containing less than 2 g protein/100 kcal and follow-up formulas based on hydrolysed protein containing less than 2.25 g protein/100 kcal should be clinically evaluated by a competent national and/or regional authority.**]

Additional comments for protein Footnotes:

Canada notes that the Footnote numbers do not appear next the relevant text, in superscript. Canada proposes that Footnote 5 regarding the minimum protein value **be re-positioned as Footnote 2,** because it relates to minimum values.

Furthermore, for Footnote 5, Canada would like to point out that the second sentence should also include non-goats' milk protein in addition to non-cows' milk protein. Canada would like to propose the following revision for the second sentence in Footnote 5:

"For follow-up formula based on non-cows' **or non-goats'** milk protein other protein minimum values may need to be applied." Canada would like to point out that the value of 0.5 g/100 kJ should be corrected to **0.54** g/100 kJ.

For follow-up formula based on soy protein isolates (SPIs), Canada would like to draw attention to IEG 2013, Table 1, which states that for formulas based on SPIs the minimum protein should be 2.1 g/100 kcal, and the maximum should be 2.5 g/100 kcal. **Note that the text in the paper suggests that the minimum protein content in FUF based on SPI should be 2.05 g/100 kcal, and in the footnote above it states 2.25 g/100 kcal, please clarify.** Further support for changing the minimum values for SPI-based formulas can also be found on page 48 of EFSA 2013: Based on concerns of lower equivalence of soy protein isolate, the minimum protein content of IF based on SPI has been set in the infant formula standard at 1.23 times the minimum of cow's milk-based infant formula while the maximum levels set are the same, although the scientific evidence to justify this choice is limited. To achieve consistency with the IF standard, the minimum and maximum protein contents in follow up formula based on SPI should be set at 2.05 g/100 kcal and 2.5 g/100 kcal, respectively.

3.3 Vitamin K: minimum requirements

Recommendation 2

Canada agrees with recommendation 2.

3.4 Vitamin C: minimum requirements

Recommendation 3

Canada agrees with Recommendation 3 and also requests clarification on whether there should be a reference to Footnote 15 following "Vitamin C" in recommendation 3. (i.e., superscript "15" following "Vitamin C" to link to "expressed as ascorbic acid").

3.5 Zinc: guiding upper level

Recommendation 4

As per Canada's previous comments, the GUL value of 1.0 mg/100 kcal as per the recently revised EU legislation would be our preference. Canada prefers a lower GUL of 1.0 mg/100 kcal because of concerns of exceeding NOAELs for zinc established by the International Zinc Nutrition Consultative Group (iZiNCG). However, Canada acknowledges that the risk of zinc toxicity is low and would not be opposed to a GUL of 1.5mg/100 kcal. Canada agrees with the proposed wording of Footnote 20. Canada agrees with the higher minimum value of 0.75 mg/100 kcal for FUF based on soy protein isolate. The inhibitory effect of phytic acid on zinc absorption is well documented.

3.6 Optional addition: DHA

Recommendation 5

Canada agrees with Recommendation 5 for the GUL of 0.5% total fatty acids, and proposes that when DHA is added, it be at a minimum level of 0.3% total fatty acids, which is the worldwide mean. Canada agrees with the proposed footnote. Canada requests clarification on whether the footnote for Recommendation 5 (DHA) (pg. 16 of Agenda Item 5) is indeed number [20)], since the footnote for Recommendation 4 (zinc) (pg. 15 of Agenda Item 5) is also number [20)]. This is likely an error and the footnote should actually be [21)].

3.7 Optional addition: L(+) lactic acid producing cultures

Recommendation 6

Canada agrees with recommendation 6.

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

4.1 Role of Product

Recommendation 7

Canada agrees with recommendation 7. Follow-up formula for older infants (FUF-OI) and follow-up formula for young children (FUF-YC) have different roles in the diet, and the nutrient requirements of these two groups differ. FUF-OI is a major component of the diet, is more nutrient dense and a significant contribution to nutrient intake. FUF-YC is more limited in terms of contribution to nutrient intake.

4.3 Optional Addition

Recommendation 8

Canada notes that the Committee has not been asked to comment on Section 5, the first part of which is copied below:

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

5.1 Overview

It is proposed that the mandatory (core) composition of follow-up formula for young children include a limited list of essential nutrients. Based on comments from the eWG, there are two different approaches: a more extensive prescriptive list of mandatory (core) nutrients, and a simplified less prescriptive approach. In order to facilitate discussion at the pWG, the Chairs of the eWG have provided a third option and recommendations for the mandatory (core) composition of follow-up formula for young children. These recommendations are based on the principles outlined in Section 4 to ensure that product contributes to the nutritional needs of young children for those nutrients which are inadequate in the diet, as well as providing the key nutrients from cows' milk and ensuring the nutritional quality and integrity of product is maintained. The recommendations are also based on the principles of less prescription and ensuring flexibility. See below for further detail on these three options.

Extensive prescribed mandatory (core) composition	**Simplified mandatory (core) composition**	**Chairs recommendation**
Energy density	-	Energy density
Carbohydrate (total and associated footnotes)	Total sugars	Carbohydrate maximum Total sugars
Fat (total and associated footnotes)	Fat quality	Fat quality
Protein (total and associated footnotes)	-	Protein quality
Calcium	Calcium	Calcium
Vitamin B12	Vitamin B12	Vitamin B12
Riboflavin	Riboflavin	Riboflavin
Iron	Iron	Iron
Vitamin C	Vitamin C	Vitamin C
Vitamin D	-	-
Vitamin A	-	-
Zinc	-	-
Sodium	-	Sodium, maximum only

Canada disagrees with the Chairs recommendations for the proposed lists of nutrients at the beginning of Section 5 (page 24 of Agenda Item 5 paper). The list of mandatory nutrients would not result in a nutritionally balanced product; therefore we would question this approach.

Under Recommendation 8, the 2 options as presented are currently not clear to Canada. We would like to propose an alternative approach:

We would prefer to extend the list of nutrients for mandatory composition and allow for the optional addition of nutrients which are less critical at a global level for this age group, as the complementary diet seems to be providing adequate intakes.

Canada would prefer that the mandatory core composition be based on equivalence to cows' milk as well as provisions for the key nutrients of global concern.

We therefore propose that the following be included as 'mandatory' nutrients (see left hand column, the other two columns are as in the table above, and were not modified):

Suggestion from Canada – More extensive prescribed mandatory (core) composition	**Simplified mandatory (core) composition**	**Chairs recommendation**
Energy density	-	Energy density
Carbohydrate* maximum **Total sugars*** **(Appropriate footnotes)**	Total sugars	Carbohydrate maximum Total sugars
Fat* minimum **Fat quality** **(Appropriate footnotes)**	Fat quality	Fat quality
Protein* minimum **Protein quality** **(Appropriate footnotes)**	-	Protein quality
Calcium*	Calcium	Calcium
Phosphorus*		
Magnesium*		
Vitamin B12*	Vitamin B12	Vitamin B12
Riboflavin*	Riboflavin	Riboflavin
Iron**	Iron	Iron
Vitamin C	Vitamin C	Vitamin C
Vitamin D **	-	-
Vitamin A***	-	-
Zinc***	-	-
Sodium, maximum only	-	Sodium, maximum only
Potassium*		
Iodine**		

***Nutrient contained in cows' milk in a significant amount**

****Nutrient of global concern in some regions**

*****Nutrient of global concern and contained in cows' milk in a significant amount**

Each nutrient or nutritional parameter should be considered for addition based on the requirements of young children and the provision of key nutrients needed by population sub-groups with nutritional deficiencies, as well as the nutrients in cows' milk. For instance, for mineral nutrients, calcium addition, along with iron, zinc and sodium would not result in a balanced product unless nutrients such as magnesium, phosphorous and potassium are also present or added.

For the proposals under "mandatory (core) composition", Canada is of the opinion that selecting nutrients from the essential composition of FUF-OI may not result in a nutritionally balanced product.

Additionally, it is not clear whether either Option 1 or Option 2 reflects our position as a starting point for the optional addition of nutrients, other ingredients or substances. Canada would like to request clarification on this. **Is this the starting point for the Committee or for National Authorities?**

The European Commission (2016) has recently defined young child formulas, milk-based beverages and similar products intended for young children 'as those products specifically processed or formulated and intended to satisfy the nutritional requirements of young children (aged 1 to 3 years), and will often replace cows' milk in whole or in part in the diet of young children.' We would like to reiterate that we do not support using the essential composition of FUF-OI as a starting point for FUF-YC given that their nutritional requirements are different and that they also have a more varied diet than older infants.

Canada would prefer that the eWG and Committee also spend more time on establishing the principles for voluntary addition of essential nutrients. This could, for instance, include ensuring that the nutrient content is appropriate for young children when the product is consumed in typical amounts. If minimum and maximum amounts are provided for each nutrient, this should provide sufficient flexibility for the manufacturer to formulate the product.

One of the original aims of the Committee was to support the formulation of products for free trade between countries, and too much variation in the Standard for FUF-YC will make that more difficult. The Revised Standard should be clear on the amounts of each nutrient that can be added to FUF-YC, to support free trade considerations and the nutritional integrity of products across jurisdictions.

5.2 Energy density

Recommendation 9

Canada agrees with the energy density requirements set out in Recommendation 9. With regard to the additional option for further discussion, Canada agrees that the separate minimum energy density for young children more than 24 months of age is acceptable.

5.3.1 Proposed requirements for minimum and maximum protein, total fat, and available carbohydrates

Recommendation 10

Canada agrees with the maximum level for carbohydrates as outlined in Recommendation 10. The proposed 12g/100 kcal would equal 48% of total energy, and would fall within the range of 45-60% total energy intake as proposed by EFSA, and the 45-65% range from the IOM.

Canada agrees that a minimum for protein should be established and we propose the following:

[The level of protein shall not be less than 5.2 g/100 kcal]

The rationale behind this minimum is that it is the lower end of the range of protein in whole cows' milk.

We believe that the option for the level of protein to be not less than 1.8 g/100 kcal to be too low for FUF-YC.

Canada agrees with setting an amount for total fat and agrees with the additional option for incorporation into the standard about the level of total fats not being less than 4.0 g/100 kcal.

Recommendation 11

Canada agrees with recommendation 11 and proposes that a superscript [1] be added after the word quality, and to refer to a revised footnote as follows: [**[1]Protein quality shall be determined provisionally using the PER or PDCAAS methods.]**

5.5.1 Essential fatty acids

Recommendation 12

Canada agrees with the minimum level of α-linolenic acid of 50 mg/100 kcal as set out in Recommendation 12. Canada also supports the use of a minimum content of linoleic acid of 500 mg/100 kcal. We would like to align with the level proposed by IEG (2015) for linoleic acid (LA) of 500 mg/100 kcal (72 mg/100 kj), and propose adding to the Standard: **[The level of linoleic acid should be not less than 500 mg/100 kcal (72 mg/100 kJ]**

Canada supports the adoption of the proposed CODEX FUF-OI guidance upper level (GUL) for LA of 1400 mg/100 kcal (335 mg/100 kJ), and propose adding to the Standard: **[The GUL for linoleic acid shall be 1400 mg/100 kcal (335 mg/ 100 kJ]**

Lauric, Myristic and Palmitic Acids

Canada notes that during the eWG consultations, discussions occurred on the above fatty acids; however the agenda paper does not make a recommendation. Canada reiterates its comments from CP2, as follows:

Canada agrees that the maximum percentage of fat for the sum of lauric acid and myristic acid should be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants. This is in agreement with IEG (2013) which noted the potential untoward effects of lauric and myristic acid on serum cholesterol and lipoprotein concentrations.

Canada proposes that a maximum level should also be established for palmitic acid. The rationale is that the effects of palmitic acid on blood lipid profile are at least as detrimental as those of lauric acid and myristic acid. While palmitic acid raises total and LDL-cholesterol in adults (which lauric and myristic acid also do), additionally palmitic acid increases the total cholesterol/HDL-cholesterol ratio (an effect that is not observed with lauric and myristic acids) (Mensink et al 2003). The total cholesterol/HDL-cholesterol ratio is considered as a better marker of cardiovascular disease risk than total cholesterol or LDL-cholesterol. In addition, the amounts of palmitic acid in cow's milk are higher (about 22-35% of fatty acids w/w, thus expected to have a relatively high impact on blood lipid profile) than the amounts of lauric (about 2-5%) and myristic (about 8-14%) (Jensen 2002). Therefore, if maximum levels are established for lauric and myristic acids on the basis of their detrimental effect on blood lipid profile in adults, maximum levels should also be established for palmitic acid. Canada proposes that the maximum level for palmitic acid should not be higher than 35% of fat, based on average cow's milk

content in Europe and North America (Jensen 2002, Soyeurt 2008, Lindmark Mansson 2008, Danish Food Composition Database, DTU Fodevareinstituttet).

1. Mensink RP, Zock PL, Kester AD, Katan MB. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. Am J Clin Nutr. 2003 May;77(5):1146-55. http://www.ncbi.nlm.nih.gov/pubmed/12716665

2. Jensen RG. Invited review: The composition of bovine milk lipids. January 1995 to December 2000. J Dairy Sci 2002; 85:295-350

3. Soyeurt H. Genetic variability of fatty acids in bovine milk, Base (Biotechnologie, Agronomie, Société et Environnement) 2008; 12 (2). http://popups.ulg.ac.be/1780-4507/index.php?id=2416

4. Lindmark Mansson H. Fatty acids in bovine milk fat. Food & Nutrition Research 2008. DOI: 10.3402/fnr.v52i0.1821. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2596709/

5. Danish Food Composition database version 7 (no longer maintained). Food code 0156. http://www.foodcomp.dk/v7/fcdb_details.asp?FoodId=0156. Accessed July 12 2016

6. DTU Fodevareinstituttet. http://frida.fooddata.dk/ShowFood.php?foodid=6&2; Accessed July 12 2016

Furthermore, the average combined content of lauric and myristic acids in cows' milk in Europe and North America ranges between 10 – 19% of total milk fat, which supports the proposed limit of ≤20% of fat.

To summarise:

Canada agrees with the question asked in CP2, that the maximum percentage of fat for the sum of lauric acid and myristic acid should be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants.

Canada proposes that a maximum level should also be established for palmitic acid. Canada proposes that the maximum level for palmitic acid should not be higher than 35% of fat, based on average cow's milk content in Europe and North America.

Canada would ask why limits for erucic acid are not to be included in the Standard for FUF-YC?

5.5.4 Trans fats and commercially hydrogenated fats and oils

Recommendation 13

Canada is in full agreement with Recommendation 13.

5.6 Types of carbohydrates

Recommendation 14

Canada is in agreement with the following text of the proposed footnote: Lactose should be the preferred carbohydrate**s** in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

However, Canada does not agree with the following text of the proposed footnote: Sugars, other than lactose, should not exceed 10% of available carbohydrate and would like to propose the following: [**Sugars, other than lactose, should not exceed 10% of available carbohydrate unless the product is plant-based or lactose-free**]

Canada agrees with the additional option: Lactose should be the preferred carbohydrate**s** in formula based on milk protein [and should provide not less than 50% of total carbohydrates]

5.7 Iron and Vitamin C

Recommendation 15

Iron

Canada supports the inclusion of iron as a mandatory nutrient addition to FUF-YC. As mentioned in the Agenda Item 5 paper, globally, iron has been found to be inadequate in sub-groups of populations (CX/NFSDU 14/36/7). Canada agrees that the minimum iron fortification level should be 1 mg/ 100 kcal (0.25 mg/ 100 kJ) and that the maximum level be established at 3.0 mg/ 100 kcal (0.7 mg/100 kJ).

Canada agrees that the minimum iron fortification level in soy protein-based FUF-YC should be 1.5 mg/100kcal (0.36 mg/100 kJ). The reduced bioavailability of iron in soy protein formula, due to its phytic acid content, is the reason for the current proposal of a 50% higher iron level in FUF-YC based on soy protein compared to the iron level based on cow's milk protein (EFSA, 2014). Therefore it is proposed that the minimum iron fortification level in soy protein-based follow-on formula be 1.5 times higher than that in cows' milk protein-based formulae. Canada also agrees to the maximum level of 3.0 mg/100 kcal (0.7 mg/100 kJ) for FUF based on soy protein isolate.

Vitamin C

Canada supports a minimum level of vitamin C fortification at 10 mg/ 100 kcal (1.0 mg/ 100 kJ) and a GUL of 70 mg/100 kcal (17 mg/ 100 kJ). If iron is to be considered a mandatory nutrient then vitamin C should also be mandatory based on its role in enhancing the absorption of iron. Previously, in CP2, Canada had suggested a minimum of 4.5 mg/100 kcal based on IEG 2015. However, the proposed maximum level of iron has increased from 2.0 mg/100 kcal to 3.0 mg/100 kcal since CP2 so Canada would not be opposed to also increasing the minimum level of vitamin C to 10 mg/100 kcal to help ensure the use of the additional iron content. The level of vitamin C also tends to decrease during the shelf-life of these products, especially in liquids, therefore increasing the minimum level would help to compensate for the degradation of vitamin C.

5.8 Key nutrients in cows' milk: calcium, riboflavin and vitamin B12

Recommendation 16

Calcium

It is Canada's opinion that FUF-YC should contain a minimum calcium level of 200 mg/100 kcal, which is close to the lower bound of the amount in whole cows' milk (184-201mg/100 kcal). The IEG (2015) has proposed a minimum calcium value of 200 mg/100 kcal. This level is equivalent to 40% of the recommended intake established by the WHO/FAO (500 mg/day).

Canada agrees to the GUL for calcium of 280 mg. This value would provide a daily amount of calcium well below the IOM UL of 2500 mg per day.

Canada agrees with including the calcium/phosphorus ratios as presented in recommendation 16. We would like to propose that the mandatory addition of calcium to a product should also require the mandatory inclusion of phosphorous, to help ensure proper mineral balance. **Canada therefore recommends setting a minimum and maximum or GUL for phosphorus, and making the addition mandatory.** The amount of phosphorus in whole cows' milk is an average of 148 mg/100 kcal, with a range of 138-153 mg/100 kcal, so these amounts should be accommodated if it is decided to include phosphorus as a mandatory nutrient.

Riboflavin

Canada supports a mandatory amount of riboflavin in FUF-YC, but proposes a minimum level of 273 µg/100 kcal, which is the lower bound of the amount in whole cows' milk (273 – 456 µg/100 kcal.

Canada agrees with the GUL proposed in Recommendation 16 of 500ug/100 kcal for riboflavin, which is consistent with the GUL of the proposed Codex Standard for FUF-OI, and which is fairly close to the upper bound of the range of riboflavin content in whole cows' milk at 456 µg/100 kcal.

Vitamin B12

Canada supports a mandatory amount of riboflavin in FUF-YC, but proposes a minimum level of 0.5 µg/100 kcal which is in line with the lower bound of the amount in whole cows' milk (0.5 – 1.4 µg/100 kcal).

Canada agrees with the GUL proposed in Recommendation 16 of 1.5 µg/100 kcal for vitamin B12, which is in line with the proposed Codex Standard for FUF-OI, and which is just above the upper bound of the range of the range of vitamin B12 content of full fat cows' milk, at 1.4 µg/100 kcal.

5.9 Zinc

Recommendation 16 (17)

Canada disagrees with Recommendation 16 (17), and supports the alternative option presented in the recommendation, that zinc should be a mandatory addition to FUF-YC.

Zinc is one of the key nutrients in cows' milk and zinc deficiency is a major public health problem in many countries (based on the WHO/UNICEF/IAEA/IZiNCG zinc indicators data on the prevalence of stunting and zinc deficiency), particularly in low and middle income countries. Therefore, Canada

supports the mandatory addition to FUF-YC. Canada agrees with the proposed minimum of 0.5 mg/100 kcal, which is close to the lower bound of the amount in whole cows' milk (0.56-0.79 mg/100 kcal and is close to the proposed minimum by the IEG (2015) of 0.6 mg/100 kcal.

Canada would prefer a lower GUL of 1.5 mg/100 kcal than that proposed (i.e., 1.8 mg/100 kcal), because of the risk of exceeding the IOM UL and the potential increased risk of zinc toxicity when this product is consumed with zinc containing complementary foods. Combined with zinc containing foods there is concern that zinc intakes will exceed ULs/NOAELs established by RASBs. For comparison, the upper bound of the amount of zinc found in whole cows' milk is 0.79 mg/100 kcal.

5.10 Vitamin A

Recommendation 17 (18)

Canada disagrees with Recommendation 17 that vitamin A should not be included as a mandatory (core) nutrient. We support the mandatory addition of vitamin A to FUF-YC, and support the minimum and maximum amounts proposed in the alternative option within Recommendation 17.

Additional comments:

Mandatory addition: Canada supports the mandatory addition of vitamin A to FUF-YC since it supports Principles 1 and 2, namely 'contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale' and 'contribution of adequate amounts of key nutrients from cow's milk'.

Vitamin A is naturally available in whole pasteurised cows' milk in moderate amounts, a range from 48 – 75 mcg RE/100 kcal, but additional vitamin A may be needed for use in countries where intakes are inadequate. The IEG 2015 states that vitamin A is often limited in the diets of young children, particularly in those in developing countries or disadvantaged groups, as they are prone to nutrient deficiencies due to inadequate and poor quality complementary feeding as well as due to infection, and they recommend the the minimum and maximum amounts in the alternative option above.

Please see Canada's response concerning our support for the mandatory addition of vitamin A to FUF-YC in CP1, which was partly based on the IEG 2015 report.

Przyrembel and Agostoni (2013) noted that complementary feeding regimens differ in countries and are determined by tradition, empirical behaviors and availability of foods. Although they stated that FUF is not needed in the diet of young children based on available evidence, they have proposed that if such a product were available, the vitamin A content should have a minimum of between 55-67 mcg RE/100 kcal, and a maximum of 182-222 mcg RE/100 kcal.

Also, it is of note that only one Codex Member Organisation did not support the mandatory addition of vitamin A to FUF-YC, their rationale was to provide for "flexibility", since it would be more appropriate for individual national authorities to require the mandatory addition of vitamin A at the national level if required to meet the specific needs of the local population. However, most of the other eWG members supported the mandatory addition of vitamin A in FUF-YC.

1. Suthutvoravut U et al. Composition of Follow-Up Formula for Young Children Aged 12-36 Months: Recommendations of an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Ann Nutr Metab. 2015;67(2):119-32.

2. Przyrembel H and Agostoni C. Growing-up milk: a necessity or marketing? World Rev Nutr Diet. 2013;108:49-55.

Minimum: Canada supports 60 mcg/100 kcal as the minimum requirement for vitamin A in FUF-YC, based on the above two references. This level of addition is equal to the average amount of vitamin A in whole cow's milk (i.e. 60 mcg/100 kcal).

Maximum: Canada supports a maximum of 180 µg RE/100 kcal, based on the above two references. Canada supports a maximum level for vitamin A, rather than a GUL, considering that the risk of adverse effects increases as intake exceeds the UL.

5.11 Vitamin D

Recommendation 18 (19)

Canada disagrees with Recommendation 18 that vitamin D not be included as a mandatory (core) nutrient and supports the alternative option for the mandatory addition of vitamin D to FUF-YC.

Canada proposes a vitamin D minimum level of 1 µg /100 kcal which is in line with the levels in the Codex IF standard and the current minimum level of vitamin D in the Codex FUF standard.

Canada proposes a vitamin D maximum of 3 µg /100 kcal, which is in line with the recommended maximum levels for vitamin D made by the Scientific Committee on Food and the European Commission for follow-up formulas. This level is the current maximum level of vitamin D in the Codex FUF standard.

Additional comments: Canada supports the mandatory addition of vitamin D to FUF-YC since it supports Principle 1, namely 'contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale'. It is mandatory to fortify cows' milk in Canada since very few foods contain this nutrient, and sunlight exposure may be limited in some population sub-groups. Since cows' milk is fortified with vitamin D in Canada, rates of insufficiency and deficiency are low. However, vitamin D insufficiency is prevalent among young children in different parts of the world.

The IEG 2015 found that young children had inadequate vitamin D intakes in parts of the world. Using serum 25-hydroxyvitamin D concentration to define vitamin D status, vitamin D deficiency (serum 25-hydroxyvitamin D <27.5 nmol/l or <50 nmol/l) was found in 10% of children aged 6-23 months in New Zealand, and in 34.9 and 42.8% of children aged 2-4.9 years in urban and rural areas of Indonesia, respectively. The IEG 2015 also reports on surveys in young children from 4 countries in Southeast Asia which showed that vitamin D insufficiency may be a problem in tropical countries, in addition to countries that are at higher latitudes such as North America and Europe. The Agenda report also indicates that vitamin D insufficiency in older infants and young children has been observed in many countries (pg. 49).

Przyrembel and Agostoni (2013) noted that complementary feeding regimens differ in countries and are determined by tradition, empirical behaviors and availability of foods. Although they stated that FUF is not needed in the diet of young children based on available evidence, they propose that if such a product were available, the vitamin D content should have a minimum of between 1 and 1.3 mcg /100 kcal, which is in line with Canada's proposed levels.

It is of note that only one Codex Member Organisation did not support the mandatory addition of vitamin D, while most of the other eWG members supported the mandatory addition of vitamin D to FUF-YC.

The DRI for vitamin D was updated by the IOM in 2011, and the UL was set at 62.5 µg/day. Assuming a daily intake of 500 ml of this product and an energy density level of about 60 kcal/100 ml, exposure data indicates that the proposed maximum of 3 µg /100 kcal would result in intakes well below the IOM UL for young children 1 – 3 years of age (i.e., calculated vitamin D intake of 9 µg / day).

1. IOM (2011). Dietary Reference Intakes for Calcium and Vitamin D.
2. IEG, Suthutvoravut U et al. Composition of Follow-Up Formula for Young Children Aged 12-36 Months: Recommendations of an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Ann Nutr Metab. 2015;67(2):119-32.
3. Przyrembel H and Agostoni C. Growing-up milk: a necessity or marketing? World Rev Nutr Diet. 2013;108:49-55.

5.12 Sodium

Recommendation 19 (20)

Canada agrees with recommendation 19 (20).

6 Scope and Labelling

Recommendation 20 (21)

Canada agrees to recommendation 20 (21), to differentiate the two products in the Scope and Labelling Section, and throughout the document.

Recommendation 21 (22)

Canada notes that there is more work to be carried out on the nutritional composition of the formulas for young children, and therefore considers that it is too early to provide an appropriate response to Recommendation 21 on proposed names for the product, 'fortified milk product' or 'processed milk product for young children' or 'follow-up formula for young children'. As these could be very different products, in term of nutrient density, for instance, we believe that this decision should be deferred. Our proposal from the 2015 comments was 'young child milk-based (or plant-based) beverage'.

In addition, Recommendation 21 goes on to say that FUF for young children 'means a product intended for use as a liquid part of the progressively diversified diet **when nutrient intakes may not be adequate to meet the nutritional requirements of young children**'. We find that the currently proposed

approach and the 3 principles being used would not of themselves ensure that a balanced product would be developed for use in young children when nutrient intakes may not be adequate. Canada proposes that this definition will depend on the final composition determined for the product, and should be deferred until this is decided on.

COLOMBIA

Recommendation 1:

Colombia agrees with the minimum value proposed 1.8g protein / 100 kcal.

Colombia maintains its previous positions regarding the maximum value 3.5 g / 100 kcal.

Recommendation 2:

Colombia agrees with the GUL proposed for vitamin K and maintains its position regarding the minimum value (4.0 g / 100 kcal).

Recommendation 3:

Colombia agrees with the GUL proposed for Vitamin C and maintains its position regarding the minimum value (4.0 g / 100 kcal).

Recommendation 4:

Colombia agrees with the minimum value of 0, 5 mg/100 kcal, and the GUL of 1.5 mg / 100 kcal.

Recommendation 5:

Colombia supports not establish a minimum level. The addition of DHA should be scientifically justified.

Also, Colombia maintains its position regarding the note:

“The ARA and EPA addition is optional and not required when DHA is added. However If ARA were to be added then its content should reach at least the same concentration as DHA. If ARA on diet is below to the ratio 1:1 with DHA, ARA should be added. If EPA were to be added its content should not exceed the content of DHA. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs. “

Recommendation 6:

Colombia maintains its position regarding the addition of acid lactic producing cultures for the two purposes.

Colombia suggests to assess the possibility of including other options of acid lactic producing cultures if the safety and suitability of the addition is demonstrated by generally accepted scientific evidence.

Recommendation 7:

Colombia maintains its position to divide the standard in two separates parts as presented in Appendix 5.

Recommendation 8:

Colombia supports option 2.

Recommendation 9:

Colombia maintains its position of minimum energy level of 45 kcal / 100 ml from the energy density of the fat skimmed cow's milk and a maximum of 70 kcal / 100 ml.

Recomendation10:

Colombia agrees to include a maximum level of carbohydrates and proposes a maximum level of total carbohydrates of 14 g / 100 kcal.

Colombia agrees with the minimum value of protein (1.8 g / 100 kcal.)

Colombia maintains its position as the maximum value of 15% of the energy from protein.

At this level the maximum energy from carbohydrates equates to 56% of energy in order to allow the formulation of a nutritionally balanced product. This level is still below the maximum carbohydrate levels set by different AMDRs proposed (IoM, WHO, Lippman)

Recommendation 11:

Colombia agrees to include the minimum quality requirements, with a value that should not be less than 80% of casein, and reiterates the importance of defining a maximum requirement of protein.

This value I proposed in accordance with Recommendations of Energy and Nutrients Intake for Colombian population and a digestibility percentage.

Recommendation 12:

Colombia agrees to include a mandatory requirement of α-linolenic acid with a value not less than 50 mg per 100 kcal.

Recommendation 13:

Colombia agrees that commercially hydrogenated oils and fats shall not be used in follow-up formula for young children

However, Colombia considers a maximum value of trans fatty acids of 3% of the total fat should be take into account.

Recommendation 14:

Colombia agrees with the text set for the types of carbohydrates

Recommendation 15:

Colombia maintains its proposed iron levels between 1.0 and 3.0 mg / 100 kcal, minimum and maximum respectively.

Colombia considers that the particular requirements for the composition of iron must be included, and a larger value is proposed than value set for 6-12 months.

For vitamin C Colombia does not agree with the recommendation and remains in the position of 4.5 mg / 100 kcal and 70 GUL mg / 100 kcal.

Recommendation 16:

Colombia agrees with the recommendation for calcium and does not agree with riboflavin and vitamin B12, maintaining the previous position.

Vitamin B12:

Minimum of 0.15mcg/100kcal aligned with Kolezko.

Minimum levels of vitamin B12 in whole milk (0.25ug/100g i.e. 0.40ug/100kcal when converted using the average energy density of whole milk at 62kcal/100g, FAO, 2013) contribute a 83% of the vitamin B12 NRV (0.9ug/day) per 300mL serve, with average levels in whole milk (0.51ug/100g i.e. 0.82ug/100kcal) contributing 170% of the NRV per 300mL serve. Similar to the approach taken for other nutrients, Colombia proposes 30% of the NRV is targeted per 300mL serve i.e. 0.13ug/100kcal when converted at the maximum energy density of 70kcal/100mL (or rounded up to ENA proposal of 0.15ug/100kcal).

Colombia supports a GUL for Vitamin B12 noting the non-specified maximum in the current Standard and the low risk of fortification for vitamin B12. The level for GUL would need to be determined once the protein levels are defined. Furthermore, this level would also need to take into account both variable B12 levels in the milk ingredients as well as shelf life losses of up to 55%.

Riboflavin

Minimum of 70 mcg / 100 kcal.

Colombia proposes that riboflavin is mandated in follow-up formula for young children on the basis this is an essential nutrient for which cow's milk is a key contributor to a young child's dietary intakes. Similar to the approach taken with other nutrients, Colombia propose that 30% of the NRV (0.5mg/day) per 300mL is targeted for minimum levels, resulting in 0.07mg/100kcal, which rounds up to the current Codex Follow-up Formula Standard.

Colombia supports a GUL for Riboflavin noting the non-specified maximum in the current standard and the low risk of fortification for Riboflavin. The level for GUL would need to be determined once the protein levels are defined and would need to take into account the inherent variability of riboflavin levels from lactose and milk protein ingredients as well as the high level of degradation for this nutrient >60% across shelf life.

Colombia does not agree to include calcium / phosphorus ratio

Recommendation 16:

Colombia maintains its position to include Zinc as a mandatory nutrient and supports the alternate option with the proposed values.

Recommendation 17:

Colombia maintains its position include vitamin A as mandatory nutrient, however, it remains in its position of minimum (60 mcg RE / 100kcal) and maximum (225 mcg RE / 100kcal).

Colombia considers a maximum of 225 mcg/100kcal is acceptable for Follow-up formula for young children on the basis of: A maximum is more appropriate than a GUL due to the potential toxicity of vitamin A; The IOM provides an upper limit of 600 mcg/day vitamin A for children aged 1-3 years old. At an energy range of 45-70kcal/100mL, the child could receive between 142.9 – 222.2 mcg Vitamin A per day. Further support for this level is provided when taking the approach to multiply the Follow-up Formula for Young Children minimum level of vitamin A (0.6mg/100kcal) by 3-5 times, providing 180 – 300 mcg/100kcal. The level of 225 mcg/100kcal is within this range

Recommendation 18:

Colombia maintains its position include vitamin D as mandatory nutrient and supports the alternative option with the proposed values

Recommendation 19:

Colombia agrees with the recommendation of sodium with a maximum level of 85 mg / 100 kcal

Recommendation 20:

Colombia agrees to divide the standard in Sections A and B, as set in Appendix 5.

Recommendation 21:

Colombia supports the denominations of:

- Follow-up formula for older infants

- Follow-up formula for young children

However, Colombia requested more precise definitions of both products.

COSTA RICA

Recommendation 1

Costa Rica supports the minimum protein level of 1.8 g/100 kcal, but it considers it important to analyse the content of the EFSA report on formula with at least 1.6 g/100 kcal before taking a decision on this value. Follow-up formula for older infants that contains a protein level of between 1.8 g and 2.0 g/100 kcal do not require clinical evaluation in line with a recent evaluation by the EFSA (EFSA 2014). The EFSA Scientific Opinion concluded that the scientific data are sufficient for demonstrating the safety of all formulas (infant and follow-on formulas) made using intact milk proteins where the protein content is greater than 1.8 g/100 kcal. (EFSA 2014) Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 12 (7): 3760).

As indicated in the document CX/NFSDU 16/38/6, there is limited evidence for establishing a maximum protein level. For this reason, Costa Rica continues to support the maximum level established by the electronic working group of 3.5 g/100 kcal. At 14%, this value does not exceed 20% of energy as protein, so it does not represent an excess renal load (EFSA 2012). However, in order to achieve a consensus, Costa Rica could support an alternate value of 3.0 g/100 kcal, which is in line with the standard for infant formula.

In addition, it supports the proposed modifications to footnotes 2 to 6.

Recommendation 2

Costa Rica supports a minimum value of 4 mg/100 kcal for vitamin K, which is in line with the proposal by Koletzko et al, 2013. (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 3

The international expert group coordinated by the Early Nutrition Academy (Koletzko et al 2013 Ann Nutri Metab 62: 44-54) concluded that there is not sufficient proof for establishing different vitamin

compositional requirements in follow-up formula compared to infant formula. Costa Rica supports this evaluation and therefore agrees with the level based on the Codex standard for infant formula.

Recommendation 4

Costa Rica supports a minimum zinc level of 0.5 mg/100 kcal and an NSR of 1.5 mg/100 kcal, both in line with Codex standard 72-1981 and also supported by Koletzko 2013.

(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 5

Costa Rica supports the inclusion of DHA as an optional ingredient. Therefore, it does not consider it necessary to establish a minimum quantity for this nutrient because of the variable level of DHA in the diversified diet of older infants. However, it supports the inclusion of references to the minimum DHA level recommended by national/regional authorities in the form of the proposed footnote.

Recommendation 6

Costa Rica supports the ability to add lactic acid producing cultures L(+) to follow-up formula for acidification purposes. It therefore supports point 1.3.2.5.

With respect to point 1.3.2.5, it believes that the addition of bacteria for other nutritional purposes should meet the criteria for other substances added as optional ingredients. Such cultures should only be added if they meet the requirements for optional ingredients. In addition, Costa Rica does not believe that all bacteria added for nutritional purposes are lactic acid producing. It therefore proposes the following additions in bold:

1.3.2.5 [The safety and suitability of the addition of specific **bacterial** strains of L(+) lactic acid producing cultures for particularly nutritional purposes, at the level of use, shall be demonstrated by generally accepted scientific evidence at the level of use. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect. **Bacterial strains added for particular nutritional purposes may be, but are not limited to L(+) lactic acid producing bacteria**.]

Recommendation 7

Costa Rica supports the proposal to divide the standard into two parts, one for follow-on formula for older infants and the other for products intended for young children. This proposal is consistent with the previous Committee discussions.

Recommendation 8

Costa Rica supports the proposal regarding compulsory compositional requirements and optional additions. With respect to optional additions, Option 2 seems to be the most appropriate and clear to us.

Recommendation 9

Costa agrees with the energy value proposed by the Chair, i.e. 60 kcal to 70 kcal per 100 ml. In addition, it supports a lower energy value for children younger than 24 months of age based on the clarifications in document CX/NFSDU 16/38/6. (45 kcal/100 ml)

Recommendation 10

Costa Rica supports the specification of a maximum limit of 12 g/100 kcal of carbohydrates to ensure that the levels of proteins and fats are in line with the levels specified by the eWG (fats: 3.56 g/100 kcal; proteins: 1.5-5.5 g/100 kcal) for the purpose of ensuring that the level of carbohydrates is not excessive. This, according to the analysis conducted by the Chair, is to ensure that in the case of low levels of fat or protein, the residual energy from carbohydrates comes from lactose (at levels equivalent to the levels in cow's milk) and less than 8 g/portion come from other nutritionally available carbohydrates.

Recommendation 11

Costa Rica supports Recommendation 11. It understands that there was no consensus in the eWG with respect to the determination of the minimum and maximum protein level, but it would support the establishment of both levels to ensure the nutritional balance of products. As suggested by the Chair of the eWG, it could support a minimum value of 1.8 g/100 kcal and a maximum based on the level of proteins present in whole cow's milk, expressed as 22% of the total energy content or 5.5g/100 kcal.

Recommendation 12

Costa Rica supports Recommendation 12, which calls for the establishment of a minimum level of α-linolenic acid of 50 mg/100 kcal, based on the evidence that there is insufficient intake of this nutrient among young children around the world. In addition, as discussed in the Committee, Costa Rica supports the establishment of a minimum level of 300 mg/100 kcal [72 mg/100 kJ]; NSR: 1,400 mg/100 kcal [335 mg/100 kJ] for linoleic acid in accordance with the requirements for formula for older infants.

Recommendation 13

Costa Rica supports the recommendation of the Chair of the working group with respect to the limit on fats and hydrogenated acids in formula for young children.

It is understood that there is no desire to set a value for trans fat acids, but they could be limited to 3% of the total fat acids in accordance with the principle of allowing the use of milk fat that appears in both the Codex Standard for formula for infants as well as in the Codex Standard for follow-up formula for older infants.

Recommendation 14

Costa Rica supports Recommendation 14, including the addition proposed for subsequent consideration regarding lactose.

Recommendation 15

Costa Rica supports Recommendation 15 regarding the establishment of minimum and maximum values for iron and vitamin C as proposed by the Chair of the eWG and in accordance with the considerations contained in the document CX/NFSDU 16/38/6.

Recommendation 16

Costa Rica supports the minimum values and guide for calcium, riboflavin and vitamin B12. However, failure to establish a minimum level for phosphorous would result in a lack of support for the addition of a relationship between calcium and phosphorous.

As expressed in the electronic working group, Costa Rica supports the compulsory addition of zinc to formula intended for young children. We therefore support the minimum values and guide that have been proposed. The expert group coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy identified zinc deficiency as a particular public health concern in developing countries with predominantly plant-based diets. Costa Rica therefore believes that it meets one of the key principles (Section 4.2 of CX/NFSDU 16/38/6) developed to support and justify compulsory nutrients in the composition of products for young children (contribution to the nutritional needs of young children when the consumption of nutrients is inadequate at the global level).

We ask the Committee to recognise that there are limitations in developing countries to carrying out studies that allow for the justification of the unilateral addition of nutrients that are not considered to be compulsory under the international standard. In the case of Costa Rica, while the last National Nutrition Survey carried out in 2008-2009 identified a zinc deficiency within the population group subject to the standard, this is the most recent data that we have at the national level. Therefore, we believe that if a reference by international experts justifies the inclusion of a particular nutrient, this should be sufficient to request its compulsory addition. This will facilitate the minimum harmonisation and standardisation of products and at the same time allow for flexibility when adding non-essential nutrients as a matter of public health. Although we have initiatives to fortify food, it may be necessary to develop new vehicles for increasing the availability of the nutrient for children in the 12 to 36-month age group, which will also involve additional costs and effort if such strategies have not already been implemented.

Reference:

Suthutvoravut U, Abiodun PO, 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, 67:119-32.

Recommendation 17

Costa Rica supports the compulsory addition of vitamin A to products for young children, essentially for the same reasons given in support of the inclusion of zinc. We agree with the proposed minimum and maximum values in the event it is accepted as a compulsory nutrient.

Recommendation 18

Costa Rica supports the compulsory addition of vitamin D to follow-up formula for young children as well as the proposed minimum and maximum values.

Recommendation 19

Costa Rica supports the proposed maximum value for sodium of 85 mg/100 kcal. On the assumption that formula for children provides 15% of daily calories and taking 1,000 mg as the upper limit (IOM 2001), we believe that this value is appropriate and that it is in line with the current standard for follow-up formula.

Recommendation 20

Costa Rica supports Recommendation 20.

Recommendation 21

Costa Rica agrees with the term and the proposed definition in Recommendation 21 for follow-up formula for older infants. However, for the second term we prefer to use follow-up formula for young children in place of the other options. In addition, the definition could be modified as follows:

[**Follow-up formula for young children**] [means a product **specially manufactured** ~~intended~~ for use as a liquid part of the ~~progressively~~ diversified diet **in order to contribute** ~~when nutrient intakes may not be to meet the nutritional requirements~~ to the nutritional needs of young **children.**]

CUBA

Cuba agrees with the document in principle.

NEPAL

1. General Comments:

During the last meeting it was decided that follow up formula will be referred to as a product and therefore throughout this document the word “food” must be replaced with the word “product”.

2. SCOPE

We recommend the following changes:

1.1.**3**~~1~~The application of Section A and Section B of this Standard shouldtake in to account the recommendations made **in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, the WHO guidance on Ending the Inappropriate Promotion of Food for Infants and Young Children and relevant World Health Assembly resolutions 32.22, 39.28, 47.5, 49.15, 54.2, 55.25, 58.32, 59.21, 61.2, 63.23, 69.9.**

1.2.**3**~~1~~ the application of Section B of this Standard should take in to account the recommendations as above

3. NAME AND DEFINITION 2.1.1

We recommend the following changes:

2.1.1 [Follow -up formula for older infants means a product**, in liquid or in powdered forms,** intended for use **as a total or partial substitute for breast milk given** ~~as the liquid part of the diet for older infants~~ when complementary feeding is introduced.]

[Follow up formula for young children OR [{name of product)] **[Fortified milk]** ~~OR [Processed milk product]~~ for young children means a product intended for use **as a substitute for breast milk in helping to meet the normal nutritional requirements of young children** as ~~a liquid~~ part of the progressively diversified diet.

Rationale:

The name of the product targeted for 6-12 months should be different than the name of the product targeted for children 12-36 months. The product for 6-12 months may be called follow up formula and therefore if the word “formula” also appears in the product targeted for 12-36 months, it may cause confusion among mothers and the product could potentially be fed incorrectly as a complete replacement for all foods. Such use of this product could have serious negative implications on the nutritional status of younger children.

The term “Processed milk product” should be deleted since processed milk product includes a range of products that may not be suitable for children 12-36 months old.

4. LABELLING 9.

In order to make coherence with other Codex standards, we propose that under Section 9. “Labelling”, following text should be added:

[**There should be prohibition on the use of nutrition or health claims in the label as per the General Standard for the Labelling of Prepackaged Foods [CODEX STAN 1-19850, the CODEX Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).**

9.1 The name of the product

We propose that following should be added:

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s) so that there is a distinction between Follow up Formula and Fortified Milk.

9.1.2 The name of the product shall be ‘Follow-up Formula for infants’ based on the composition of the product. In addition, thereto, any appropriate designation may be used in accordance with national usage.

Rationale:

The text of the label and all other information accompanying the product greatly influence the mothers/caregivers on feeding the baby. Therefore, it is necessary for buyers to be informed through the label on the specific product for the specific age group.

[9.6 Additional [Labelling] Requirements:

~~The products covered by this standard are not breast milk substitutes and shall not be presented as such.~~

9.6.1 The label of the product shall be prepared in such a manner as to give necessary information about the proper uses of the product and not to discourage breastfeeding. Each label shall have a clear, conspicuous and easily readable message which includes the following points:

- **a) The words “important notice” or similar other matters;**
- **b) The statement “breast milk is the best food for infants;**
- **c) A statement that the product is not the sole source of nourishment of an infant and should only be used on advice of a health worker.**

9.6.2 The label shall have no pictures of infants and women or any other picture or text which idealizes the use of the product.

9.6.3 The terms “humanized”, “maternalized” or other similar term shall not be used.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, fortified milks for older children and formula for special medical purposes. This includes, but is not limited to, using the same logos, icons, color schemes or terms such as ‘stage 1,2,3’]

Rationale:

We strongly believe that these products are Breast Milk Substitutes since they either totally or partially replace breastfeeding once complementary feeding begins and the global guidance is clear that breastfeeding should continue beyond exclusive for 6 months to at least 2 years and beyond. This is important in promoting optimal breastfeeding. Furthermore, several evidences suggest that insufficient information and/or presenting mis-information has led caregivers/mothers to inappropriately feed the children. This is also coherent to the WHA guidance on “ending inappropriate marketing of foods for infant and young children, ”which was adopted as part of WHA 69.9 this year.

NEW ZEALAND

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

Recommendation 1: Protein requirements

At this point in time, New Zealand supports the minimum protein requirement proposed in the Agenda Paper of 1.8 kcal/100 kcal and the associated proposed changes to the footnotes. As noted in the Agenda Paper, New Zealand acknowledges that whilst the evidence is developing in this area, there is a lack of strong scientific evidence currently available to support a lower minimum. The lower minimum

of 1.8 g/100 kcal has been evaluated to be safe and suitable for this age group, however we do note the pending scientific opinion from EFSA looking at a lower protein level of 1.61 g/100 kcal which will need to be considered by the Committee once the report has been released.

With regards to the maximum protein requirement, New Zealand supports a level of 3.5 g/100 kcal but would not oppose a maximum of 3.0 g/100 kcal.

Recommendation 2: Minimum level for vitamin K

New Zealand supports alignment with the Codex Standard for Infant Formula with respect to the minimum vitamin K level in follow-up formula for older infants and therefore agrees with the level proposed in the Agenda Paper; 4.0 µg/100 kcal.

Recommendation 3: Minimum level for vitamin C

New Zealand supports the recommendation to adopt a minimum vitamin C level of 10 mg/100 kcal to align with the Codex Infant Formula Standard. There is insufficient evidence to demonstrate the global nutritional suitability of, or need to decrease the minimum to 4 mg/100 kcal.

Recommendation 4: Minimum, GUL and footnote for zinc

New Zealand supports the recommendation to adopt a GUL of 1.5 mg/100 kcal in alignment with the Codex Standard for Infant Formula. This GUL is applicable to all types of follow-up formula for older infants, including those based on soy protein isolate.

Evidence provided by eWG members suggests that there is a low possibility that the zinc GUL specified in the Codex Infant Formula Standard would lead to any impairment in the nutrient absorption of iron or copper. In addition to this several eWG members noted that technological feasibility is not an issue for zinc within the range 0.5 - 1.5 mg/100 kcal, whereas if the GUL was to be lowered, this would result in a narrow range for formulation which may be technologically difficult to accommodate.

Recommendation 5: DHA

New Zealand supports the recommendation in the Agenda Paper that no minimum level is required to be established. The principle that substances should only be added to formula at levels that are effective and achieve the intended effect will ensure that appropriate levels of DHA are added. This is also consistent with the approach for all other optional ingredients. Furthermore, footnote 20 enables competent national and/or regional authorities to deviate from the conditions specified in the Standard. This allows minimum levels of DHA (either as an optional or mandatory addition) to be specified by competent national and/or regional authorities based on the population's nutritional needs.

Recommendation 6: Optional addition of L(+) lactic acid producing cultures

New Zealand supports an approach which permits and clarifies the two purposes for the addition of L(+) lactic acid producing culture to follow-up formula for older infants: the technological function, and for a nutritive purpose. We therefore agree with the recommendation, with minor editorial amendments, and revised wording in the Agenda Paper which states the following:

> **[1.3.2.4** Only L(+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants.
>
> **1.3.2.5** The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particular**[ly]** nutritional purposes, at the level of use, shall be demonstrated by generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect.

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

Recommendation 7: Two separate parts for the Standard

New Zealand supports the proposed new structure for the Standard for Follow-up Formula, with Section A referring to the essential composition and labelling of follow-up formula for older infants, and Section B dealing with the essential composition and labelling of product for young children. New Zealand is of the view that this approach will allow for clear distinction and differentiation of the two product categories; follow-up formula for older infants and product for young children, by allowing for different composition and labelling approaches to the two different product categories.

Recommendation 8: Revised framework for the essential composition of follow-up formula for young children and preferred option for the optional addition of other nutrients

New Zealand supports the revised framework presented in the Agenda Paper, and considers the three principles for the determination of the mandatory compositional requirements for follow-up formula for young children critical to establishing which nutrients should be considered mandatory additions.

New Zealand also supports the additional text which clarifies that competent national and/or regional authorities may require additional mandatory nutrients required to meet local dietary needs. It is considered that this statement may be best placed within Section 3.1 Essential Composition rather than 3.2 Optional Ingredients.

With regards to the optional addition of other nutrients, New Zealand's preference is for OPTION 1. Option 1 enables additional essential nutrients to be added to follow-up formula for young children and refers to the composition of follow-up formula for older infants as a reference point for nutrient levels unless scientific [or technical] justification warrants deviation. New Zealand supports this approach as it provides a framework and guidance for levels that should be chosen for the optional addition of nutrients whilst still enabling some flexibility where scientifically or technically justified. Further to this, manufacturers may also add other ingredients and substances provided their safety and suitability for the particular nutritional purpose, at the level of use, is evaluated and scientifically demonstrated. Optional ingredients and substances must also be present at levels that achieve the intended effect.

New Zealand is aware that for some nutrients, the nutrient range established for follow-up formula for older infants, may not be nutritionally appropriate or technically feasible for follow-up formula for young children, and therefore we support the inclusion of a clause which allows for the nutrient levels established for follow-up formula for older infants to be 'amended if the nutritional needs of the population and scientific [or technical] justification warrants deviating from the level stipulated for older infants'.

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

As outlined above, the preferred proposal for the optional addition of other essential nutrients to product for young children is that these nutrient additions are chosen from the essential composition of follow-up formula for older infants with corresponding levels as the starting point. In the proposed standard for follow-up formula for older infants, all essential nutrients have both a minimum and a maximum or GUL stipulated. None of the essential nutrients have a N.S. (not specified) limit. Therefore, the optional addition of other essential nutrients would require that these levels are met (if Option 1 is the preferred option). For the purposes of consistency, it may be appropriate that either maximums or GULs are specified for those micronutrients included in the essential composition of follow-up formula for young children.

Recommendation 9: Requirements for energy density

New Zealand supports specifying energy requirements for follow-up formula for young children in order to ensure the appropriate energy density of products targeted to this age group and fully supports the maximum energy density proposed of 70 kcal/100 mL.

New Zealand is aware that country guidelines for milk consumption from the age of 12 months can differ regarding appropriate fat content (i.e. full fat and reduced fat milk). In many countries, the local nutritional guidelines for young children recommend full fat milk from the age of 12 months. In New Zealand the Ministry of Health recommends whole milk as a suitable source of fluid and expressly discourages the use of reduced fat milk in the diet for toddlers between the ages of one and two years. From two years of age, and as long as they are growing well, young children can transition from whole milk to reduced fat milk (MoH 2008).

New Zealand is open to further discussion at the Committee as to the appropriate minimum energy level for follow-up formula for young children. However we encourage the Committee to come to a conclusion on this issue as the results of this decision have flow on effects for the remaining recommendations. The Committee will need to decide whether we consider the nutrient content of both full fat and reduced fat cows' milk when proposing nutrient ranges for follow-up formula for young children.

Recommendation 10: Maximum limit for total carbohydrates

New Zealand agrees that a minimum carbohydrate level does not need to be prescribed by the Standard, and supports prescribing a maximum level only, as a means of limiting excess added sugars and added refined carbohydrate ingredients.

New Zealand is of the view that a maximum limit of 14 mg/100kcal for this age group may be unnecessarily high considering the eWG concerns regarding excess sugar in the diets of this age group. The new recommendation in the Agenda Paper states that the level of available carbohydrate should

not exceed 12g per 100kcal. New Zealand supports lowering the maximum limit but understands that 12 g/100 kcal may be too low from a manufacturing tolerance perspective to enable moderate protein and fat formulations, and is therefore open to discussions around a slightly higher maximum level for available carbohydrate of 12.5 g/100 kcal.

The Agenda Paper presents an approach whereby of the macronutrients, only a maximum available carbohydrate content is defined within the Standard. This aligns with the principle to establish a more flexible standard, and also helps ensure a nutritionally appropriate contribution from carbohydrate in follow-up formula for young children. If the Committee wishes to establish a more prescriptive Standard which mandates the fat and protein content of the product, the Agenda Paper recommends that consideration is given to establishing minimum levels. The Agenda Paper therefore presents additional options for minimum levels for protein and total fat for further discussion.

Whilst New Zealand could support the establishment of a minimum protein level, it supports the approach presented in the Agenda Paper whereby it is not necessary to include a maximum limit for protein in the Standard. Should the consensus of the Committee be to include a minimum protein level, New Zealand supports the option presented in the Agenda Paper where the level of protein is aligned with the minimum requirement specified for follow-up formula for older infants (once confirmed).

Dependent on the decision around minimum energy density levels and if the Committee supports establishing a minimum level for fat, New Zealand recommends that consideration is given to a level of 3.5 g fat/100 kcal to align with the upper levels in reduced fat milk, as an alternative to the minimum level of 4 g fat/100 kcal recommended in the Agenda Paper.

Recommendation 11: Minimum protein quality requirements

New Zealand is fully supportive of deriving minimum protein quality requirements for product for young children. It is noted that the eWG have had difficulty in deriving protein quality requirements for this age group and that some element of consistency is required across the standard. As such it could be useful for the Committee to explore the option of requesting assistance from JEMNU regarding protein quality specifications for this product category.

Alternatively, a more comprehensive approach could be sought and the Committee could explore requesting advice from JEMNU as to how the most recent findings of the FAO document Dietary Protein Quality in Human Nutrition (2011) could be incorporated across all applicable Codex Standards. As highlighted previously a range of methods are used in assessing protein quality across Codex Standards and there would be benefit in seeking consistency where appropriate. In addition to this the FAO report highlighted that for the purposes of Codex, a quality assessment should be applied to protein content claims for the purposes of nutrition labelling.

Recommendation 12: Mandatory requirement for the addition of α- linolenic acid

New Zealand does not oppose the recommendation to establish a minimum ALA content of 50 mg/100 kcal and does not consider it necessary to mandate the addition of linoleic acid to product for young children based on data on dietary intakes.

New Zealand wishes to highlight an error in the calculation of α-linolenic acid (ALA) presented in this section of the Agenda Paper. The calculated daily requirements were out by a factor of 10:

This equates to a daily intake of **3183 - 4775** mg of linoleic and **424 - 637** mg of α-linolenic acid based on the energy requirements of young children aged 12-36 months.

Recommendation 13: Commercially hydrogenated fats and oils

New Zealand supports the recommendation in the Agenda Paper that commercially hydrogenated oils and fats shall not be used in follow-up formula for young children. This approach will effectively eliminate sources of industrially produced trans fatty acids from these products, as well as enabling products to be predominately based on cows' milk. This approach is also aligned with the principle of managing the the nutritional quality and integrity of product to ensure nutritional safety.

Recommendation 14: Types of carbohydrates

New Zealand agrees with the recommendation in the Agenda Paper that lactose should be the preferred carbohydrate in follow-up formula for young children based on milk protein; and that sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

New Zealand strongly supports an approach which limits the addition of carbohydrates to these products, particularly around the use of mono- and di-saccharides and those carbohydrates with similar metabolic and sweetening effects. We support the proposal to have a specified limit on the contribution

of sugars other than lactose. As proposed in the Agenda Paper it is preferable to specify the limit as a percentage of available carbohydrates for the purposes of consistency. This approach is consistent with the Codex Standard for Infant Formula and Section A of the proposed Standard for Follow-up Formula for older infants.

Regarding the contribution of sugars other than lactose, New Zealand notes that the decision around the maximum available carbohydrate content may influence this (i.e 14 g or 12 g carbohydrates per 100 kcal). It is noted that a maximum of 10% energy contribution from sugars other than lactose would equate to 2.5 g /100 kcal; this is equivalent to a limit of 20% of nutritionally available carbohydrates (at a maximum of 12.5 g/100 kcal) (the requirement for follow-up formula for older infants). A maximum limit of 10% of nutritionally available carbohydrates would equate to 1.25 g or 1.4 g/100 kcal based on a limit of 12.5 and 14 g/100 kcal respectively.

New Zealand's preference is for a reduction in the maximum available carbohydrate content to 12.5 g/100 kcal, at this level a limit of 20% of carbohydrates from sugars (other than lactose) could be supported. This approach would substantially limit the addition of free sugars and also other types of carbohydrates which can have a similar metabolic and sweetening effect (ie. maltodextrin) which within Codex are not classified as sugar.

New Zealand propose deleting the requirement that: [Only precooked and/or gelatinised starches gluten-free by nature may be added]. As this age group will be consuming a variety of complementary foods, many of which contain gluten.

Proposed amended wording:

[Lactose should be the preferred carbohydrate in [name of product] based on milk protein. ~~Only precooked and/or gelatinised starches gluten-free by nature may be added~~. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source. Sugars, other than lactose, should not exceed **[**10%**] or [20%]** of available carbohydrate].

Recommendation 15: Recommendation for iron and vitamin C

New Zealand supports the mandatory addition of iron to product for young children due to evidence of inadequate intakes of iron in this age group globally. New Zealand supports the levels proposed in the Agenda Paper; minimum 1.0 mg/100 kcal, maximum of 3.0 mg/100 kcal. New Zealand also agrees that a maximum level rather than a GUL be adopted to ensure that the potential adverse effects of high iron intakes on the absorption of other essential nutrients is minimised.

For the reason of aiding iron absorption, New Zealand also supports the mandatory addition of vitamin C to product for young children at the levels being proposed for adoption by the Committee for follow-up formula for older infants; minimum 10 mg/100 kcal, GUL 70 mg/100 kcal.

Recommendation 16: Recommendation for calcium, riboflavin and vitamin B12 levels

One of the principles for the determination of the mandatory compositional requirements for product for young children is evidence to support the contribution of adequate amounts of key nutrients from cows' milk, where such nutrients are key contributors to the diet of young children. Cows' milk is a major contributor to calcium, riboflavin, and vitamin B12 requirements of young children – providing over 70% of a young children's requirement in a 300 mL serve. New Zealand therefore agrees that calcium, riboflavin and vitamin B12 should be mandatory additions to product for young children as follow-up formula for young children is often used as a substitute for cows' milk.

Calcium:

New Zealand is of the view that the minimum level of calcium must be able to provide a significant contribution of calcium to the young child's diet, as well as accommodate the average calcium content in cows' milk. New Zealand therefore supports a minimum of 90 mg/100 kcal.

In line with the principle of flexibility a GUL of 280 mg/100 kcal has been proposed to enable those products based predominantly on cows' milk to be accommodated. This levels represents the upper range of calcium in reduced fat cows' milk. New Zealand is happy to support this recommendation.

In line with the principle of flexibility and limited evidence on the need for phosphorous to be added to follow-up formula for young children, New Zealand is in agreement that a calcium to phosphorous ratio does not need to be established.

Riboflavin:

The Agenda Paper recommends that the minimum and GUL for riboflavin specified in the proposed standard for follow-up formula for older infants is applicable for follow-up formula for young children,

with a minimum and GUL ranging between 80-500 µg/100 kcal. Whilst New Zealand can support the proposed minimum level of 80 µg/100 kcal, we would ask that consideration be given to a higher GUL of 650 µg/100 kcal to better reflect the variable levels of riboflavin present in reduced fat and whole cows' milk.

Vitamin B12:

New Zealand supports the proposal in the Agenda Paper that the requirements for vitamin B12 in follow-up formula for young children are able to accommodate the compositional requirements of follow-up formula for older infants and the vitamin B12 content of cows' milk. In order to do so, a minimum of 0.1 µg/100 kcal should be established and GUL of 2.0 µg/100 kcal. The minimum requirement is aligned with the proposed standard for follow-up formula for older infants, and the GUL represents the upper bound of the range of vitamin B12 contained in reduced fat cows' milk.

Recommendation 16: Zinc should not be included as a mandatory (core) nutrient

New Zealand agrees that zinc should not be included as a mandatory (core) nutrient for addition to product for young children as its addition does not appear to fulfil any of the three principles that have been developed for determining the mandatory compositional requirements. New Zealand considers that the mandatory addition of zinc should only be considered if deemed necessary by individual national authorities for their local population. Zinc deficiency does not appear to be a global issue.

Recommendation 17: Vitamin A should not be included as a mandatory (core) nutrient

New Zealand agrees that vitamin A should not be included as a mandatory (core) nutrient for addition to product for young children as its addition does not appear to fulfil any of the three principles that have been developed for determining the mandatory compositional requirements. Of note is the fact that vitamin A deficiency is not a global issue. Vitamin A deficiency is relatively rare in European countries, the USA and Canada. For this reason, New Zealand is of the view that the mandatory addition of vitamin A to product for young children should only be required if deemed necessary by individual national authorities for their local population. This approach will also allow individual countries to factor in the contribution of vitamin A from any fortification programmes that may be operating in the local area.

Recommendation 18: Vitamin D should not be included as a mandatory (core) nutrient

New Zealand agrees that vitamin D should not be included as a mandatory (core) nutrient for addition to product for young children. It is worth noting that the eWG has previously highlighted that regional differences exist in vitamin D requirements, and in the prevalence of inadequate vitamin D status.

New Zealand therefore considers that the mandatory addition of vitamin D to product for young children should only be required if deemed necessary by individual national authorities for their local population. This approach will allow individual countries to factor in the contribution of vitamin D from different public health approaches that are being used to address vitamin D insufficiency, including the use of supplementation programmes used in some countries.

Recommendation 19: Recommendation for sodium maximum

New Zealand is happy to support the inclusion of a maximum level for sodium in product for young children for the purpose of maintaining the nutritional integrity of the product. Based on the collective comments from the eWG and need to accommodate cows' milk, New Zealand supports the Chairs recommendation of establishing a maximum level of 85 mg/ 100kcal.

Recommendation 20: Division of the Standard for Follow-up Formula in to two separate parts

New Zealand supports the proposed new structure of the Standard for Follow-up Formula, with Section A referring to the essential composition and labelling of follow-up formula for older infants, and Section B dealing with the essential composition and labelling of product for young children. New Zealand is of the view that this approach will allow for clear distinction and differentiation of the two product categories; follow-up formula for older infants and product for young children, by allowing for different composition and labelling approaches to the two different product categories.

Recommendation 21: Definition 2.1.1

New Zealand is supportive of separate definitions for the respective product categories within the Standard for Follow-up Formula as it has become apparent that distinctively different product names which are easily distinguishable, based on the diverse roles in the diet that these products play will assist in differentiating the two different product categories. New Zealand also supports the view presented by the majority of the 2016 eWG, in that product for young children should not be considered a 'formula' as this confuses product for young children with formula marketed and suitable for use by infants in the first

year of life. New Zealand's preferred definitions are listed below. New Zealand is of the view that further discussion and consideration of the name of product for young children needs to occur.

Follow-up formula for older infants *means a product intended for use as the liquid part of the diet for older infants [as either a breast milk substitute or a replacement for infant formula] when complementary feeding is introduced, and*

[Name of product] for young children *means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.*

NORWAY

Specific Comments

Recommendation 1: Protein

1) Minimum amount

We support a minimum of 1.8 g protein/100 kcal. We also support considering the results of the forthcoming opinion by EFSA on the safety and suitability of consumption of lower protein formulas containing 1.61 g protein/100 kcal, before finalising a minimum requirement.

2) Maximum amount

We are of the opinion that a maximum of 3.0 g protein/100 kcal is too high. We continue to support a maximum level of 2.5 g/100 kcal in milk based formula, which is in line with EFSA and the European Commission Delegated Regulation (EU) 2016/127 on Infant Formula and Follow-On Formula. We consider there is no need to exceed a maximum limit of 2.5 g/100 kcal. A representative caloric intake of 500 kcal/day would correspond to 12.5 g protein per day, exceeding the requirement of 10.2 g per day. In addition to this, complementary feeding would also provide some protein. Furthermore, high protein intakes should be avoided in order to reduce possible associated risks.

3) Footnote 3

We are of the view that breast milk should be used as a reference protein, and supports to refer to Annex I of the Infant Formula Standard.

4) Footnote 5

We support a minimum value of 2.25 g/100 kcal for follow-up formula based on soy protein isolate, which is in line with EFSA and the EU Regulation on Infant Formula and Follow-On Formula.

5) Footnote 6

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

For formula based on non-hydrolysed protein, we consider that clinical evaluation is not necessary for a minimum amount of 1.8 g protein. This is in line with EFSA 2014. We suggest that the EFSA review on the safety and suitability of consumption of lower protein formulas containing 1.61 g protein/100 kcal in follow-up formulas, should be considered before deciding whether clinical evaluation is needed for a lower minimum amount.

Recommendation 2: Vitamin K

We continue supporting a minimum vitamin K content of 1 µg/100 kcal, which is based on the EFSA opinion from 2014 and which is in line with the new EU Regulation on Infant Formula and Follow-On Formula.

The EFSA recommendation is based on the recommendation that a vitamin K intake of 5 µg per day is adequate for the majority of young infants (0-6 months). NNR 2012[6] refers to that new-borns should routinely be given vitamin K to avoid haemorrhage during the neonatal period, and that oral prophylaxis should be continued for the first three months. We are not aware of haemorrhagic problems in healthy children from 6 months, and therefore do not consider haemorrhagic problems as a justification for the minimum amount of vitamin K in the age group of 6-12 months.

[6] Nordic Nutrition Recommendations 2012

Recommendation 3: Vitamin C

We continue supporting a minimum vitamin C content of 4 mg/100 kcal, which is based on the EFSA opinion from 2014 and is in line with the new EU Regulation on Infant Formula and Follow-On Formula.

Recommendation 4: Zinc

We are still in favour of a GUL of 1.0 mg zinc/100 kcal, which is in line with the new EU Regulation on infant formula and follow-on formula. A GUL 1.0 mg would avoid exceeding the UL of 5 mg/day for infants 7-12 months[1]. In line with this, we support a maximum of 1.25 mg zinc/100 kcal for follow-up formulas based on soy protein isolates.

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

Recommendation 5: Optional addition of DHA

During the discussions, we have supported mandatory addition of DHA, in line with EFSA and the new EU Regulation on Infant Formula and Follow-On Formula. EFSA has recommended that DHA should be added to all infant and follow-up formulas, in the range of 20-50 mg/100 kcal. Dietary surveys also show that it is likely that essential fatty acids are inadequate in the diets of older infants and young children.

In the light of diverging views on a minimum amount for optional addition of DHA, we support a footnote allowing national and regional authorities to deviate from the conditions in the FUF standards, including requiring mandatory addition.

Recommendation 6: Optional addition of L(+) lactic acid producing cultures

In our view, L(+) lactic acid-producing bacterial cultures may be used for the purpose of producing acidified follow-up formula for older infants.

While probiotic microorganisms survive the passage through the digestive tract, most lactic acid producing bacterial cultures do not survive this environment. Therefore, the use of non-pathogenic L(+)-lactic acid producing cultures for the manufacture of acidified milks is in most cases of no concern.

The safety and suitability of follow-up formula supplemented with lactic acid producing probiotic cultures is not fully demonstrated (see further elaborations on this below). As probiotic lactobacillus strains might be used for acidifying purposes, we consider it important to restrict the criterion in point 3.3.2.4 to only cover use for technological purposes. Consequently, we propose to include this statement in section 3.3.2.4:

The acidified final formula product should not contain significant amounts of viable L(+) lactic acid-producing bacteria, and residual amounts should not represent any health risk.

In our opinion, probiotic bacteria should not be added to follow-up-formula.

We do not disagree with the proposed criteria in 3.3.2.5 that safety and suitability should be demonstrated, and that this should be done for the specific strains and at the level of use.

However, as stated before, our view is that safety and suitability is not fully demonstrated for the use of probiotics in follow-up formula. Due to the fact that infants are vulnerable, and that there still is scientific uncertainty whether there are long-term negative effects, we consider a cautious approach appropriate.

There is insufficient information to draw conclusions on beneficial effects on infant health of the probiotics strains added to follow-up formula[1]. EFSA has additionally stated that there is no necessity to add probiotics to follow-on formulae. Several analyses have concluded that there are insufficient data to recommend the routine use of probiotic-supplemented formula.

Several risk assessment organs has concluded that there is currently no scientific evidence of adverse effects of probiotic-supplemented formula to healthy infants[1-5]. However, they also stated that there is insufficient data and that further evaluations of safety in long-term studies are needed.

The early composition of the human gastro-intestinal tract microbiota can have long-lasting functional effects. From birth to 24 months, and especially after weaning, more than 1000 bacterial species are normally established in the intestinal tract. This individual intestinal microbiota is continuously influencing the host and the host's immune system, establishing physiological functions and defence mechanisms.

The infant's diet comprises a restricted variety of foods which often are taken several times a day during a period of life when a stable intestinal flora is not yet established.

A daily intake of probiotics may have negative effect on establishment of intestinal bacterial flora and development of intestinal functions and mucosal immune system in infants and young children.

At this background, we basically consider a cautious approach appropriate at Codex level. Even though we do not disagree with the suggested principles in section 3.3.2.5, we are of the opinion that these are currently not fulfilled for probiotics in follow-up formula. We are therefore unsure whether section 3.3.2.5 should be included in the standard.

References:

1. EFSA 2014. Scientific opinion on the essential composition of infant and follow-on formulae.

2. Braegger et al.; ESPGHAN Committee on Nutrition 2011. Supplementation of infant formula with probiotics and/or prebiotics: a systematic review and comment by the ESPGHAN committee on nutrition. J Pediatr Gastroenterol Nutr. 2011 Feb;52(2):238-50.

3. Bundesinstitut für Risikobewertung (BfR) 2015. Infant and follow-on formula: no evidence for health benefits of probiotic additives. BfR opinion No. 025/2015 of 14 August 2015.

4. Opinion of the Norwegian Scientific Committee for Food Safety 2016. Health risk assessment of a food supplement containing Lactobacillus reuteri Protectis®.

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

Recommendation 8: Revised framework for essential composition of FUF for young children

We support option 1.

In the European Economic Area (EEA) it has recently been concluded that there is no need to lay down specific requirements for young-child formulae. Already existing general EEA legislation is considered to sufficiently cover such products.

EFSA has stated that young-child formulae have no unique role in the diet, and that formula consumed during the first year of life can continue to be used by young children. In Norway, it is advised that young children from 12 months are given family foods.

While the non-necessity of follow-up-formula is established at global level, we are still is of the opinion that a global standard for FUF for young children will contribute to safe products of good quality that are properly marketed.

We generally support the proposed framework of a mandatory (core) composition, which is based on those nutrients where there is evidence to suggest that young children may have difficulty in achieving adequate intakes at global level. Furthermore, we support flexibility for national authorities to mandate other nutrients, based on levels indicated in the standard for follow-up formula for older infants.

With regards to the optional addition of other nutrients, ingredients or substances to follow-up formula for young children, we support that such additions are chosen from the essential composition of follow-up formula for older infants (**option 1**). This is based on the recommendations by EFSA that formula consumed during the first year can continue to be used by young children. In our opinion, this option will provide more guidance, and to a bigger extent ensure that follow-up formula for younger children are safe.

We support the suggestion to delete the third bullet point in preference for a principle based approach rather than inclusion of any nutrients in a list.

Recommendation 21:

To differentiate between products for older infants (6-12 months) and young children (12- 36 months) we support the name of product to older infants (6-12 months) being **[Follow-up formula for older infants].** We are of the opinion that this name of the product protects the target group and maintains the purpose and intentions of these products.

For young children between 12-36 months we suggest that the product name of this group being **[Processed milk product for young children].** We believe that this product name covers the intention and definition of the products intentions. However, we are of the opinion that the name "Fortified milk product" might mislead the consumer and idealize the product. “Fortified milk product” might for some consumers be perceived as normal cow milk fortified with for example vitamin D.

PHILIPPINES

General Comments:

The Philippines supports the Recommendations 1 to 22.

RATIONALE

Specific Comments

Recommendation 1

The Philippines support Recommendation on the proposed maximum protein content of 3.0 g/100 g consistent with our previous position. This is aligned witht the Codex Standard for Infant Formula

We support footnote 2 and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products and hence the **removal of the square brackets in footnote 2.**

We agree that minimum levels for amino acids should be included in footnote 3 using the amino acid composition of breast milk as a reference (breast-milk as defined in Annex Iof the *Standard for Infant Formula* (CODEX STAN 72-1981) and hence, **removal of the squre brackets in footnote 3**

We also support Footnote 4 on the minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) for soy-based follow-up formula if the nitrogen conversion factor of 5.71as proposed in Footnote 2 is adopted.

The Philippines supports Footnote 5:

For formula manufactured from protein hydrolysates, the minimum limit of 1.8g shall be adopted for follow-up formula. Following the approach recently set in the Commission Directive 2013/46/EU and in the Codex Standard for infant formula, the suitability of a formula shall be clinically evaluated in case of a formula with a protein content below 2.25g/100kcal for formula manufactured from cow's milk protein hydrolysates and should be**evaluated for safety and suitability and data reviewed by a competent national and/or regional authority.**The scientific substantiation, should demonstrate the safety and suitability of a formula for this particular age group to which the formula is designed for.

We support consideration of adopting this footnote as it defines a solid scientificbasis to assess the nutritional suitability and safety of use of follow-up formula for older infants with lower minimum protein levels, given protein is a critical nutrient in supporting adequate growth and development

The Philippines supports Footnote 6 with modification:

Follow-up formula based on non-hydrolysed milk protein containing 1.65-1.8 g protein/100 kcal should be clinically evaluated and **data reviewed by a competent national and/or regional authority**.

Recommendation 2

We support the proposed minimum (4.0 g/100 kcal) and Guide Upper Limit (GUL) of 27 g/100 kcal for Vitamin K since this was our previous position.

Recommendation 3

The Philippines support the minimum value of Vitamin C (10 mg/100 kcal) based on the Codex Standard for Infant Formula. We support the proposed GUL (70 mg/100 kcal).It is better to set up GUL since we have to consider vulnerability of this age group but GUL should be the same for both liquid and powdered formulas.

Recommendation 4

We support the proposed minimum and GUL values of Zinc consistent with our response to previous consultation papers.

The Philippines supports a minimum and GUL for zinc at 0.5 mg/100 kcal and 1.5 mg/100 kcal, respectively, based on data regarding the technological feasibility as well as the recommendation of the International Expert Group coordinated by the Early Nutrition Academy (Koletzko, 2013).

We reiterate our support for the minimum, guiding upper level, and associated footnote for zinc to ensure that requirements would be met in case of low quality complementary food. We support a higher level for zinc due to high prevalence of stunting and infection among older infants particularly in developing countries. The most problematic nutrients in developing countries are iron and zinc (Suthutvoravut, 2015).

Recommendation 5

The Philippines reiterate our support for the optional addition of DHA. We are in agreement with The Guidance Upper Limit (GUL) of 0.5% of fatty acids since it is identical to the maximum level set in Infant Formula Codex standard (in which DHA is an optional ingredient only). Thus, a GUL of 0.5 could be acceptable.

However, we also support inclusion of a footnote stating that national authorities may deviate from these range level and establish minimum requirements for the optional addition of DHA based on current generally established scientific evidence. In this way, the national/regional authorities are given the discretion to mandate minimum or maximum DHA levels based on the nutritional needs of its population. Consistent with our previous position, we propose a minimum DHA level of 3% of total fatty acids (AFSSA, 2010; FAO, 2010)

Recommendation 6

The Philippines support addition of only lactic acid producing cultures for both acidification and supplementing with probiotics of provided that safety and suitability is established based on current scientific evidence.

We support the use of “It is also recommended that another clause should specify that the probiotic is added for acidification to serve as technological purpose. The technological purpose (acidification of formula) in adding lactic acid producing cultures is already well-accepted even in the Infant Formula standard.

When added for nutritional purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect.

Recommendation 7

We agree with the separation of the Standard for Follow Up Formula into two parts- Part A. Essential Composition and labeling for older infants (6-12 months) and Part B. Essential Composition and labeling for young children (1-3 years) to address different physiological and nutritional needs of both groups.

Since the two standards are connected and in one way or another, they should be aligned with each other. In this way, users can easily reference to the two standards for any differences and similarities.

Recommendation 8

The Philippines supports Recommendation 8 on the revised framework on mandatory core l composition of follow up formula proposed approach and that any addition must be based on safety and suitability.

For national authorities requiring the mandatory addition of other essential nutrients for their specific population, these nutrients should be chosen from the essential composition of follow-up formula for older infants. We support **removal of the square brackets in Option 1**

We support the principle that would allow deviation from the level stipulated for older infants if the nutrient needs of the local population and scientific justification warrant it since adjustment has to be made for some nutrients which are inadequate in a particular country. Though, physiological requirements of this vulnerable age group are the same, intakes vary from country to country.

We continue to support the following key principles:

- Nutrients with known deficiencies of global and regional concerns should be considered in determining the mandatory composition (e.g. Vitamin A and Iodine in developing countries).
- Nutrients which are essential in the growth and development of older infants should also be the primary consideration.
- In considering the nutritional composition of follow up formula, the young child’s diet which include complementary foods and family foods should be considered

Recommendation 9

We support an approach that mandates the energy range of the product and levels for macronutrients based on the above proposed principles. The proposed levels in g/100kcal are equivalent to using % energy from macronutrients.

We could support an energy density of follow up formula for young children at a minimum of 60 kcal/100 ml based on older infants and full fat cow’s milk since deficiency in energy intakes still exist in some developing countries.

We agree with the establishment of a maximum energy density for follow up formula for young children at 70 kcal/100 ml.We fully supports that, when prepared ready for consumption in accordance with the instructions of the manufacturer, the product shall contain per 100 mL not more than 70 kcal (293 kJ).

The Philippines does not support having a cut-off point at 24 months of age since the proposed range of 60-70 kcal/100 ml is acceptable.

Recommendation 10

The Philippines support a maximum limit of 12 g/100 kcal (2.9 mg per 100 kJ) for total carbohydrates to ensure nutritionally appropriate contributions from follow-up formula for young children. This is consistent with the recommendation of Suthutvoravut et al, 2015 that available carbohydrates should contribute 9-14 g/100 kcal with >50% from lactose.

We are of the opinion that minimum and maximum requirements for protein are necessary. The Philippines supports 10-12% of energy from protein based on WHO recommendation and also taking into account the young child's total diet intakes.

The Philippines supports the proposed minimum fat level at 3.5 g/100 kcal which is closely similar to the levels found in breastmilk and concur with the requirements for older infants by 2014 EPZA and 2015 IEG.

Recommendation 11

The Philippines agrees that it is important to define minimum protein quality requirements within the Standard. However, **the quality of protein shall meet a protein quality score of 1.0 or 100% using the appropriate reference amino acid pattern for this age group as reported by (FAO, 2013)]**

The use of the FAO (2013) reference amino acid scoring pattern for young children, assesses the ability of a protein used in young child formula to meet their age specific amino acid requirements. The pattern is developed from assessment of amino acid requirements in the age range specified and achieving a quality score of 1.0 or 100%. This then indicates that the protein/food provides a suitable amount of essential amino acids to meet the minimum requirements of the young child.

The excerpt below from FAO (2013) highlights the 6-36month amino acid reference pattern that would need to be met by the young child formula in order to ensure appropriate protein quality. Further consideration could be given to additional adjustment the protein quality score for bioavailability by ileal amino acid digestibility or, as outlined by the Chair, true fecal digestibility. This should be established by considering the nutritional requirements, upper safe protein intake levels, dietary protein intake levels and history of apparent safe use, as well as global implications of the recommendations.

Why it is not appropriate to continue with the current FuF Standard reference to protein quality as not less than 85% of that in casein?

While the Chair has recommended simply that 'the quality of the protein shall be not less than 85% of casein", without the use of the additional footnote specifying methodology, in reality this means that protein quality would likely still be determined by PER as per the current FuF Std.

Protein Efficiency Ratio (PER) is a well-known method to assess protein quality by means of an animal (rat) growth model, feeding a known quantity of protein to infant animals over the course of 28 days. The score is a ratio of the weight gained relative to the protein consumed. It is typically adjusted for a controlled protein, the animal nutrition research council (ANRC) Casein, which is a hydrochloric acid casein. However, the PER is an old method and has not been considered gold standard for over 40 years. Most recent recommendations promote the use of a (chemical) amino acid scoring method, typically with correction for the bioavailability of the protein with measurement of the digestibility of the protein or amino acids.

Recommendation 12

That CCNFSDU agree to include a mandatory requirement for the addition of α- linolenic acid as follows:

The level of α-linolenic acid (in the form of glycerides) should not be less than [50 mg per 100 kcal (12 mg per 100 kJ)]

The Philippines supports the proposed level of α-linolenic acid since it aligns with the proposal for follow-up formula for older infants. Also this is in consideration of the limitation of this fatty acid in the diets of young children globally

Recommendation 13

That CCNFSDU agree to limit commercially hydrogenated fats and oils with the following statement:

[Commercially hydrogenated oils and fats shall not be used in [name of product] for young children].

We support the retention of the statement "Commercially hydrogenated oils and fats shall not be used in [name of product] for young children". We strongly recommend prohibiting the use of commercial hydrogenated oils and fats in follow up formula for young children. We aim for virtual elimination of any

source of trans fat in early life primarily due to its adverse health effects of trans fat on blood lipoprotein profiles and coronary heart disease.

Recommendation 14

The Philippines is in agreement with the bracketed statements that lactose should be the preferred carbohydrates in follow up formula based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 10% of available carbohydrates or 5% of total energy content. These statements are consistent with other Codex Standard for Infant Formula and Codex Standard for Cereal Based Foods for Older Infants and Young Children.

Restriction on sugar is also based on 2015 WHO recommendation that both adults and children reduce the intake of free sugars to less than 10% of energy and conditionally recommended a further reduction to less than 5% of energy.

Recommendation 15

We support a wider range of iron broader than the values set for 6-12 months old infants and recommend a GUL of 3.0 mg/100 kcal as recommended by the 2015 IEG for formula based on cows' milk protein.

We are in agreement with a minimum level of 4.5mg/100kcal for vitamin C as suggested by ENA, and which corresponds to 15% of the FAO/WHO DRI is supported due to the role of vitamin C in iron absorption. There may be no need to set maximum or GUL for vitamin C since there was no reported excessive intakes among young children.

Recommendation 16

The Philippines supports the recommended levels on th e following:

Calcium

The Philippines reiterates our support for a Calcium minimum level of 200 mg/100 kcal for follow-up formula for young children, based on an average consumption of 300 ml/day and the energy density of whole cows' milk. This is equivalent to about 40% of the recommended intake established by the WHO/FAO (500 mg/day).

Riboflavin

We support a minimum level of 80µg/100kcal, which corresponds to around 15% of the FAO/WHO DRI seems to be appropriate.

We support a GUL of 500 ug/100 kcal based on WHO/FAO INL98 value for young children

Vitamin B12

A minimum level of 0.15 µg/100kcal as suggested by ENA, and which also corresponds to 15% of the FAO/WHO DRI seems to be appropriate.

We support the proposed GUL of 1.5 ug/100kcal is sufficient since the GUL proposed by 2015 IEG is close to the Vitamin B12 content of cow's milk

The Philippines also support the proposed calcium to phosphorus ratio since is consistent with the current Codex Standard for Follow up Formula and the latest EPZA recommendation.

Recommendation 17

The Philippines maintains its position that zinc should be included as a mandatory nutrient in FUF for young children (12-36 months) The International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy has identified zinc deficiency as a public health concern and has noted that It is of particular concern in developing countries, where plant based diets predominant. For this reason it meets one of the key principles (section 4.2 CX/NFSDU 16/38/6) developed to help guide and justify mandatory (core) composition (contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale).

A minimum zinc level of 0.6mg/100kcal as proposed by ENA 2015 seems to be appropriate. A GUL OF 1.5 mg/100 kcal zinc is recommended due to widespread zinc deficiency across all countries whether low, middle or high income.

We also agree with the mandatory addition of Vitamin A to follow up formula for young children Vitamin A deficiency is still widespread particularly among this age group in developing countries around the world. The International Expert Group Coordinated by the Nutrition Association of Thailand and the Early

Nutrition Academy has identified Vitamin A deficiency as a public health concern. For this reason it meets one of the key principles (section 4.2 CX/NFSDU 16/38/6) developed to help guide and justify mandatory (core) composition (contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale).

We agree with the minimum value of 60 µg RE/100 kcal which is 15% of the RNI (400 µg) established by the WHO/FAO (Suthutvoravut, 2015).

The Philippines supports this maximum level for vitamin A due to the potential toxicity of excessive vitamin A intakes. Similar to follow-up formula for older infants, a maximum of 180 µg RE/100 kcal, which corresponds to 3 times the minimum level seems to be appropriate.

Recommendation 18

A mandatory addition of vitamin D to follow-up formula for young children at a minimum of 1.5µg/100kcal as proposed by ENA is supported by the Philippines. Vitamin D insufficiency in young children still exist even in some lower latitude countries.

A maximum of 4.5mcg/100kcal, which corresponds to 3 times the minimum level seems to be appropriate GUL level. We believe an upper limit for vitamin D is needed due to the potential toxicity of Vitamin D.

Recommendation 19

We support a minimum value of 25 mg/100kcal for Sodium based on 2015 IEG recommendation.We also support the proposed maximum value of 75 mg/100 kcal based on 2015 IEG recommendation.

Recommendation 20

The Philippines in in agreement to divide the the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. Section A will refer to the essential composition and labelling of follow-up formula for older infants, and Section B will deal with the essential composition and labelling of product for young children. It is clear from the start that the Standard will have two separate guidelines specific for older infants and young children. In each section, both have the same structure of having essential composition and labeling.

Recommendation 21

The Committee will need to finalise the product definitions (section 2.1.1).

The following definitions have been proposed by the Chairs, taking into account the need to differentiate between product for older infants and young children

[Follow-up formula for older infants *means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced, and*

[Fortified milk product] *OR* ***[Processed milk product for young children]*** *OR* ***[Follow-up formula for young children]*** *[means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.]*

The Philippines supports the retention of the bracketed statements with modifications to wit**"Follow-up Formula for young children*means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children."*** We propose the brackets on the definition of Follow-up Formula for older infants.

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UNITED STATES OF AMERICA

The United States supports the use of the nutrient standards provided in the Infant Formula Standard (CODEX STAN 72 – 1981), as the standard for Follow-up Formula (FUF) intended for older infants (6-12 months). We continue to support the recommendation to use the Infant Formula Standard as the starting point for determining the essential composition of FUF for the older infant (FUF-OI) and adjusting minimum, maximum, or guidance upper levels (GUL) as appropriate, based on scientific evidence.

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

Recommendation 1:

The United States supports **Recommendation 1** regarding the minimum, maximum levels of protein as well as Footnotes 2, 3, 4, 5, 6, as proposed. Protein quality is considered to be as important as the protein quantity and we consider the amino acid pattern in human milk to be the appropriate profile for

the older infant. We support inserting Annex 1 of the Codex Infant Formula Standard (CODEX STAN 72-1981) into the proposed Follow-up Formula Standard for the older infant (6-12 months; FUF-IO).

We consider it appropriate to retain the concept that any hydrolysed protein should be clinically tested for growth, tolerance, and adverse events, since protein hydrolysates are manufactured by different processes, resulting in products which may vary in nutritional adequacy, particularly if the protein is not a cow milk protein. We also consider clinical evaluation of 1.65-1.8 g protein/100 kcal necessary since there are very limited data available for such products.

We support Footnote 6 edited to read as follows: [Infant formula based on non-hydrolysed milk protein containing less than 1.65-1.8 g protein/ 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated].

Recommendation 2:

The United States supports **Recommendation 2** for the level of Vitamin K in FUF-OI that aligns with the current Codex Infant Formula Standard of 4 ug/100 kcals (CODEX STAN 72-1981) and is not aware of any new evidence that would support lowering the level of Vitamin K.

Recommendation 3:

The United States supports **Recommendation 3** for the minimum level for Vitamin C of 10 mg/100 kcal and supports removal of the square brackets. We believe this is nutritionally appropriate throughout the first year of life. Although there is some data to indicate a lower level may be adequate for infants in some countries, a worldwide standard should consider the needs of all populations and sources of Vitamin C from other foods may not be available or adequate from the developing diversified diet and the limited intake of the older infant.

Recommendation 4:

The United States supports **Recommendation 4** for the minimum level of zinc. This level is supported by data regarding the history of safe use in infant formula and is aligned with the zinc GUL in the Codex Standard for Infant Formula (Codex STAN 72-1981). Additionally, a GUL of 1.5 mg/100 kcal is aligned with the proposal for the nutritional composition of follow-up formula for older infants as established by the International Expert Group coordinated by the Early Nutrition Academy [1]. We support removal of the brackets around the GUL.

Recommendation 5:

The United States continues to support the information agreed to at CCNFSDU37 (2015) in the footnote regarding the relationship among DHA, ARA, and EPA as written in **Recommendation 5.** DHA and ARA should be at least at the same concentration and the content of EPA should not exceed the content of DHA. As an optional ingredient, if DHA is added, it should be added at a level that is associated with a scientifically supported positive physiological outcome(s) in the older infant (6-12 months). We also support setting a GUL for this optional ingredient as at 0.5% of total fatty acids.

Recommendation 6:

The United States supports **Recommendation 6, to** separate the two purposes of the addition of L(+) lactic acid producing cultures. This separation avoids confusion and identifies the two purposes of L(+) lactic acid use (i.e., for acidification of the formulation and for demonstrable positive physiological effects). We would appreciate clarification on the meaning of "particularly nutritional purposes" in 3.3.2.5. We consider it important to have scientific evidence supporting the addition of specific microorganisms which demonstrates the purported beneficial physiological effects, and note that these effects are not necessarily considered to be "nutritional."

Recommendation 7:

The United States supports **Recommendation 7** to separate the Follow-up Formula Standard into two parts and the approach provided in Appendix 5. Section A will refer to the essential composition and labelling of follow-up formula for older infants (6-12 months), and Section B will deal with the essential composition and labelling of product for young children (12-36 months). We agree with the differentiation (in relation to essential compositional requirements) at 12 months of age due to different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to that of young children.

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

Recommendation 8:

The United States supports Option 1 as suggested in **Recommendation 8** including the deletion of the third bullet. We favor of a principles-based approach instead of using lists of ingredients. We consider that allowing for the voluntary addition of other essential nutrients provides needed flexibility for addressing differing needs in the product's composition. However, we note that too much flexibility could become problematic when setting a "standard" for the 12-36 month old product and could render such a "standard" meaningless, by making products so diverse that it could lead to consumer confusion regarding their appropriate use.

Recommendation 9:

The United States supports **Recommendation 9** on the energy level range per 100 ml of not less than [60 kcal (250 kJ)] and not more than 70 kcal (293 kJ) and the removal of the square brackets around the 60 kcal (250 kJ). The period between 12 and 36 months of age is a transitional period in which the complementary diet advances. We consider it important that the total energy level allows for protein utilization for growth and maintenance and not as a source of energy.

Recommendation 10:

The United States supports further discussion regarding Recommendation 10. We note that the amount of carbohydrate would be constrained by the percentages of the other macronutrients and would like clarification on total versus available carbohydrate maximum levels.

The United States supports a "level of protein shall not be less than 1.8 g/100 kcal" and supports removal from the square brackets.

We also support "level of total fats shall not be less than 4.0 g/100 kcal" and removal from the square brackets. We note that there are concerns about the development of obesity that have resulted from the suggestion that reduced fat cows' milk may be appropriate for children in this age group when there is a family history of obesity, the child is gaining excessive weight, or the level of saturated fat intake is of concern. Thus, the recommendation for the fat content of milk varies, depending on the individual. There are various recommendations in the age span of 6 to 36 months and above. For example, the American Academy of Pediatrics recommends that low fat or reduced fat milk not be started before two years of age (24 months) in order that the caloric demands of growth and development may be met [2]. The 2015-2020 Dietary Guidelines for Americans 2 years and older as well as recommendations developed by other countries recommend a healthy eating pattern that includes: Fat-free or low-fat dairy, including milk, yogurt, cheese, and/or fortified soy beverages. (https://health.gov/dietaryguidelines/2015/guidelines/executive-summary/). The United States supports a minimum level of 4.0 g/100 kcal for total fat to allow for products designed for young children at least 24 months of age and to provide flexibility in the level of fat for products designed for the 12 to 24 month old.

Recommendation 11:

The United States supports **Recommendation 11** regarding the protein quality. We consider it appropriate to have a protein quality requirement for FUF for young children. For the purposes of this product for this age group, the statement included in 3.2.1.1 from the current FUF Standard (CODEX STAN 156-1987) "The quality of the protein shall not be less than 85% of that of casein" would provide adequate assurance that the protein quality requirement would be met, regardless of the protein source. We support the removal of the square brackets.

Recommendation 12:

United States supports **Recommendation 12** to include the level of α-linolenic acid (in the form of glycerides) of not less than [50 mg per 100 kcal (12 mg per 100 kJ)] and supports the removal of the square brackets. We consider the inclusion of "(in the form of glycerides)" appropriate so that it is clear that the addition of α-linolenic acid is from oils that contain α-linolenic acid. The dietary intake data provided by the Chairs of the eWG indicate that the risk of inadequate intake of linoleic acid is not a concern; however, the ratio between these essential fatty acids should be further considered and discussed since the synthesis of the long chain polyunsaturated fatty acids is influenced by the amount and ratio [3].

Recommendation 13:

The United States supports **Recommendation 13** to limit commercially hydrogenated fats and oils. However, we would appreciate clarification on why a numerical limit is used, rather than a restriction to a percentage of total fatty acids of up to 3%, as described in Footnote 8 of the Infant Formula Standard (CODEX STAN 72-1981). We are concerned that a product with a lower fat content could have more trans-fatty acids if a numerical limit is used rather than a percentage of total fatty acids.

Recommendation 14:

The United States supports **Recommendation 14** that the main source of carbohydrates should be lactose unless the product is not milk based. **Recommendation 14** appears predicated on non-hydrolyzed cow milk and that is not the only source of protein for these products. Therefore, we find the wording in the first option indicated by square brackets somewhat confusing.

For example, if soy protein isolate is used, it would not be compatible to use lactose and an alternative carbohydrate source would be needed. However, if the wording in the first option "Sugars, other than lactose, should not exceed 10% of available carbohydrate" then this wording appears to constrain the carbohydrate sources in a soy protein isolate product to 10 %. What carbohydrate would then be allowed in a soy product? We suggest consideration of the wording as follows: [Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sugars, other than lactose, should not exceed 10% of available carbohydrate in cow milk based products. Sucrose, glucose polymers and/or fructose should not be added, unless needed as a source of energy from carbohydrate].

Recommendation 15:

The United States supports **Recommendation 15** and the levels proposed for minimum and maximum iron content and the minimum level of 1.5 mg/100 kcal (0.36 mg/100 kJ) for soy protein isolate products based on the lower absorption of iron. We note that Vitamin C is known to enhance iron absorption and a worldwide standard should consider the needs of all populations as sources of Vitamin C from other foods may not be available or adequate from the developing diversified diet. We support the minimum level for Vitamin C content and the removal of the square brackets for iron and Vitamin C levels.

Recommendation 16:

The United States supports **Recommendation 16** for calcium, riboflavin, and Vitamin B12 and supports setting GULs for these nutrients. We consider that mandatory inclusion of calcium in a product for young children is needed so that bone mineralization is not compromised during this time of growth, and recommend using the CODEX STAN 72-1981, page 14, Annex II- General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula as a resource for this purpose. Further, we support the minimum and maximum ratios of calcium to phosphorus because imbalance in calcium and phosphorus levels can lead to poor bone mineralization and other issues.

We note that the riboflavin content in cows' milk is rather variable and support its inclusion. However, we are also concerned about the levels of other vitamins that are heat labile and would support further discussion and clarification on the levels of other heat labile vitamins.

Further, we consider Vitamin B-12 and its addition particularly important if the product is based on plant protein sources. We note that there is considerable variability in the amount of Vitamin B-12 in cows' milk.

Recommendation 16 continued:

The United States supports the alternative option provided in **Recommendation 16** for zinc and its inclusion as a mandatory nutrient. We note that zinc was identified as a nutrient of global concern for young children. The relationship among the micronutrients in this product should be considered to avoid potential interactions and to be consistent with the General Principles.

Recommendation 17:

The United States supports the alternative option mandating a Vitamin A level in FUF for young children in **Recommendation 17.** We note that the deficiency of Vitamin A is a major nutritional problem for this age group in developing countries and are uncertain that there is adequate evidence that other Vitamin A interventions would cover this deficiency. Cows' milk in the United States is fortified with Vitamin A at a level of not less than 60 mcg/dl (2000IU/quart; 21 CFR 131.110(b)(1)). Vitamin A is critical for vision as an essential component of rhodopsin, a protein that absorbs light in the retinal receptor as well as other functions.

Recommendation 18:

The United States supports the alternative option in **Recommendation 18** for the mandatory addition of Vitamin D, particularly if the product is to be a cow milk alternative. All cows' milk in the United States is fortified with Vitamin D at a level of not less than 1.06 mcg/dl (400 IU/quart; 21 CFR 131.110(b)(2)). We note that under Appendix 1 Table 1, a non-fortified average for Vitamin D was listed.

Vitamin D is required for calcium absorption and is also involved in maintaining bone mineral homeostasis as well as regulating renal calcium excretion. The U.S. supports a maximum level to be consistent with the General Principles and suggests that the level of Vitamin D currently added to cow milk be considered as a guide for levels in this product.

Recommendation 19:

The United States supports **Recommendation 19** for a maximum level of Sodium of 85 mg/100 kcal, 20 mg/100 kJ.

6. SCOPE & LABELLING

Recommendation 20:

The United States supports **Recommendation 20** and considers it important to recognize that there are two categories of products intended for two different populations. Creating separate sections in the Standard for each population would allow for parallel tracks for individualizing each product category when needed. For example, the essential composition and quality factors and the labelling requirements for each product category can be specified for the intended population, when appropriate. We support including a preamble statement to introduce this document to improve clarity on its use and purpose for the reader. The items in the scope section could then be tailored as appropriate for the two categories of products.

The United States supports aligning the scope for follow-up formula for older infants (6-12 months) with the current Codex labelling requirements for Infant Formula. Additionally, for young children (12-36 months), we would support aligning elements contained in the scope with the Infant Formula Standard that would include: Application, Intended Role of Products, Exclusions, Form of the Food, and Use Must Be in Accordance with Other Policies. We recommend that the scope and labelling provisions be clearly stated with the modifications addressing the different uses of the product category based on the age of the intended consumer to prevent misuse or misrepresentation of the product.

Recommendation 21:

The United States supports **Recommendation 21** for the product definitions (section 2.1.1) for each age group with further discussion regarding the product name for young children.

References:

1. 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**(1): p. 44-54.

2. Kleinman, R.E. and F.R. Greer, eds. Pediatric Nutrition. 7th ed. 2014, American Academy of Pediatrics: Elk Grove village, IL.

3. Makrides, M., et al., A randomized trial of different ratios of linoleic to α-linolenic acid in the diet of term infants: effects on visual function and growth. The American Journal of Clinical Nutrition, 2000. **71**(1): p. 120-129.

AOCS - American Oil Chemists Society

The American Oil Chemists Society, as an international organization committed to developing and upholding methods of analysis used in global trade and research, respectfully submit this position paper regarding Agenda Item 5 "Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987)"[1] with particular reference to section 3.2.3 which describes the Footnote on Protein Conversion Factors to be considered at the upcoming meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

In the proposed standard for Follow-Up Formulas, Footnote 2 refers to use of nitrogen to protein conversion factors (NCFs) for the measurement of protein content based on nitrogen determination methods. The footnote, refers to the use of a NCF of 5.71 for soy which is not aligned with the Codex standard for soya proteins nor with conventional practice and formulation of infant and follow-up formulas, where the recognized NCF of 6.25 for soy is stipulated. In the "Review of the Standard for Follow-Up Formula (Codex STAN 156-1987)"[1] published in September 2016 by the electronic working group (section 3.2.3), there is a statement indicating that the standard align with the Infant Formula Standard and that the square brackets around the NCF of 5.71 for soy protein be removed. While the electronic working group did point out that "It is important for the Committee to consider the outcomes of the CCMAS report with regards to the conversion factor for soy protein which remains in square brackets and the potential for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors", it seems incongruous to then propose to

remove the square brackets around a NCF of 5.71 for soy. We would therefore like to request the CCNFSDU to respect the recommendation of the CCMAS which was presented to the CODEX ALIMENTARIUS COMMISSION in July 2016. Due to resource limitations, FAO/WHO could not take on the task of convening an expert panel as a priority, so until scientifically justified and consistent NCFs for proteins are evaluated, we submit that the existing NCF of 6.25 for soy as reported in CODEX standards for soy protein (STAN 174-1989)[2] and vegetable protein (STAN 174-1989)[3] should be retained and that there should be no reference to a NCF of 5.71, which is currently only utilized in some specific regional standards. It should also be noted that the European Commission Scientific Committee on Food states the use of a NCF of 6.25 for soy in their "Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae"[4].

One should be aware that it is regrettable that the phrase: "…value of **5.71** as a specific factor for conversion of nitrogen to protein in other soy products" was retained in the Codex standard for Infant Formulae[5]. As noted above, an NCF value of 5.71 is not aligned with the NCF in the Codex general standard for soya proteins, and is not the factor that is actually used for soy protein in either the Codex standard for infant formulae or in the standard for follow-up formulae. We request therefore that the confusing reference to 5.71 in Footnote 2 in the Codex standard for Infant Formulae should not be perpetuated in Footnote 2 in the Codex standard on Follow-up Formula and re-iterate that reference to a NCF of 5.71 for soy should be removed from Footnote 2.

Were a NCF of 5.71 actually be used for soy in either follow-up formulae or infant formulae, it would have very significant trade and potentially serious nutritional implications. Soy protein isolate, as currently used in infant and follow-up formula products, would have to be re-categorized as a protein ingredient due to an approximate 10% reduction in the calculated amount of protein that it would apparently contain. This would likely necessitate costly formulation and/or label changes for manufacturers of follow-up formula in order to maintain the declared protein levels in their products. Furthermore, the use of a 5.71 conversion factor for soy could potentially lead to significant nutritional consequences, since lowering the NCF for soy to 5.71 would necessitate an increased inclusion of soy protein in formulas to maintain the listed protein levels. This is counter to recent recommendations to reduce the protein content for follow-up formula in the aforementioned CCNFSDU eWG "Review of the Standard for Follow-up Formula (CODEX STAN 156-1987)"[1], to reduce protein requirements for infants and young children by the FDA in the USA[6] and similar recent recommendations published by an international expert panel of pediatric nutritionists[7]

Data substantiating our position is provided in this room document.

2. PERSPECTIVES OF REGULATORY AND SCIENTIFIC ORGANIZATIONS

Use of the 6.25 nitrogen conversion factor for soy protein is widely recognized as the appropriate factor in product standards and nutritional labeling regulations that have been established by international organizations, such as Codex Alimentarius, and government regulatory agencies in India, Japan, Korea, the European Union, the United States, Argentina, Brazil, Mexico, Malaysia and South Africa (Table 1). Although an exhaustive list of regulations from around the globe is not provided in this document, the data provided represent the nutrition labeling regulations for countries ranked in the top 50 for population, hence a large proportion of the global population[8].

The 2007 FAO/WHO Compendium of Codex Standards for Cereals, Pulses, Legumes, and Vegetable Proteins[9] and other current Codex standards specifically state that the 6.25 conversion factor should be applied to calculate protein values for soy and vegetable protein products. Namely:

- 175-1989 "Codex General Standard for Soy Protein Products"[2]
- 174-1989 "Codex General Standard for Vegetable Protein Products (VPP)[3]
- CAC/GL 2-1985 "Guidelines on Nutrition Labelling" (as amended by the 29th Session of the Commission, 2006)[10]

Codex Standard 175-1989[2] is widely accepted and followed by the isolated soy protein industry. Additionally, the 90% minimum protein level stated in Codex Standard 175-1989[2] serves as an important product standard to help identify high value isolated soy protein.

Table 1. Current Soy Protein Conversion Factors from Around the Globe

Organization/Country/Region	Standard/Regulation	N Conversion Factor
Codex	Codex General Standard for Soy Protein Products STAN 175-1989[2]	6.25

Codex	Codex General Standard for Vegetable Protein Products (VPP) STAN 174-1989[3]	6.25
Codex	Guidelines on Nutrition Labelling CAC/GL 2-1985[10]	6.25
Argentina	Laws for the Labeling and Advertising of Food: Resolution in Conjunction with SPRyRS 149/2005 y SAGPyA 683/2005[11]	6.25
Brazil	Brazil National Health Surveillance Agency (ANVISA). Resolution – RDC No. 268, September 22, 2005[12]	6.25
China	China Ministry of Health "GB5009.5 Determination of Protein in Food"[13]	6.25
European Union	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers[14]	6.25
India	Lab. Manual 3, Manual of Methods of Analysis of Foods, Cereal and Cereal Products, Directorate General of Health Services Ministry of Health and Family Welfare, Government of India[15]	6.25
Japan	Japanese Agricultural Standard for Vegetable Protein and Seasoned Vegetable Protein[16]	6.25
Republic of Korea	Nitrogen Conversion Factors for Protein Calculation, Korea Food Code[17]	6.25
United States	Title 21 Code of Federal Regulations Part 101.9[18]	6.25
Mexico	Norma Oficial Mexicana NOM-051-SCFI/SSA1-2010, Especificaciones generals de etiquetado para alimentos y bebidas no alcoholicas preenvasados[19]	6.25
Malaysia	Laws of Malaysia P.U. (A) 437 of 1985; Food Act 1983; Food Regulations 1985 (amended 2015); Malaysian Ministry of Health's 2010 Guide to Nutrition Labelling and Claims[20]	6.25
South Africa	Regulations No 146 Labelling and Advertising to food stuffs – Guidelines (2010)[21]	6.25
Russia	Sanitary Epidemiological Rules and Normatives SanPiN 2.3.2.1078-01[22]	6.25

Application of the 6.25 nitrogen conversion factor to soy protein analyzed by Kjeldahl, modified Kjeldahl, and combustion methods is widely recognized by international organizations, such as Codex Alimentarius and FAO[23,24], and technical associations, such as the American Oil Chemists Society (AOCS), AOAC International (AOAC), AACC International (AACC), and the International Organization for Standardization (ISO).

The Codex Standard 234-1999 "Recommended Methods of Analysis and Sampling" (as amended by the 30th Session of the Commission, 2007)[23] lists AOAC 955.04D method that recognizes 6.25 for soy protein, as the recommended protein measurement method for soy and vegetable protein products. Furthermore, Codex Standard 234-1999[23] specifically states the 6.25 conversion factor should be applied to nitrogen values for soy and vegetable protein products obtained using AOAC 955.04D.

AOCS, AOAC, AACC, and ISO analytical methods are widely recognized by regulatory agencies in enforcement of national regulations, as well as by university and government researchers. The current protein analytical methods approved by membership consensus in these technical associations list 6.25 as the nitrogen conversion factor for soy protein (Table 2).

Table 2. Official AOCS, AOAC, AACC, and ISO Soy Protein Analytical Methods

Current Protein Analytical Method	Recommended Nitrogen Conversion Factor
AOCS Ac 4-91[25](Revised 2011)	6.25
AOCS Ba 4d-90[26](Revised 2011)	6.25
AOCS Ba 4e-93[27] (Revised 2011)	6.25
AOCS Ba 4f-00[28] (Revised 2011	6.25
AOCS Ba 4a-38[29] (Revised 2011)	6.25
AOCS Ba 10-65[30] (Reprinted 2009)	6.25
AOCS Ba 10a-05[31] (Reprinted 2009)	6.25
AOAC 988.05[32] (Revised 2012)	6.25
AOAC 992.23[33] (Revised 2005)	6.25
AACC 46-10.01[34](Reapproval 1999)	6.25
AACC 46-11.02[35](Reapproval 1999)	6.25
AACC 46-16.01[36](Reapproval 1999)	6.25
AACC 46-30.01[37] (Reapproval 1999)	6.25
ISO 16634-1:2008[38]	6.25

3. A PERSPECTIVE ON THE CHALLENGES TO A NCF OF 6.25 FOR SOY AND MEASURING PROTEIN CONTENT IN FOODS IN GENERAL

What pressures, scientific or economic, are driving the requests to change the NCF for soy from 6.25 to 5.71? What public health or other benefits would justify the significant investment in time and money required to conduct this exploration? Further, if there is a consensus that there is a critical need to conduct further assessment of the appropriate NCF for soy protein, then, in the interests of protecting the health of infants, young children and consumers in general, we believe the same exercise should be conducted for **all** commonly consumed proteins and the results of this work should be released and implemented into all of the appropriate Codex Standards in order to ensure harmonization and clarity.

It appears that the primary impetus to change NCFs for specific proteins may be economic. However, there is no current consensus method for calculating NCFs for proteins but that has not deterred investigators from using different approaches to come up with specific NCFs. For instance, a recent publication by Angell, et al., 2016[38] made the case that a specific NCF should be made for all seaweed products arguing that it is important to do so when the seaweed industry (as a protein source) is in its infancy to prevent potential economic losses (presumably to protein ingredient competitors). The economic consequences of establishing specific NCFs for proteins was highlighted by Koletzko and Shamir[40] in a commentary about a standard for infant formula quoting the German dairy industry, as saying, "the application of a NCF of 6.25 instead of 6.38 for all dairy products would lead to a loss of some €80m" for the dairy industry in Europe alone". Therefore, as novel dietary sources are introduced into the global market[41], there will be increasing pressure to develop new NCFs for these proteins. The issue of identifying appropriate nitrogen conversion factors has already arisen in the Codex Committee on Fish and Fishery Products (CCFFP) at their 34th session. The committee requested FAO to develop a table of nitrogen factors for fish species and the FAO has issued a call for data for "Elaboration of a table of nitrogen factors for quick frozen fish sticks, fish portions and fish fillets including procedure for determining nitrogen factors"[42] This additional example indicates that the issue of developing specific NCFs for proteins continues to arise, presumably out of economic concerns. Therefore, it would seem most reasonable to develop a global consensus method as to how to measure protein content for all foods. We submit that a NCF is an *operational definition* which, to date, still lacks a clear detailed

definition. An *operational definition* requires that a defined method as to how to collect data is accepted and consistently implemented, otherwise we will see the ambiguity that arises for calculating NCFs for different proteins in the absence of such a clear definition, which will be addressed later in this document.

The critical nature of establishing a consensus on the procedure to calculate NCFs is most evident in the recently published Standard Tables of Food Composition in Japan (STFCJ) 2015[16] where none of the NCFs calculated by sum of the anhydrous amino acids for any of the foods were equal to 6.25. In fact, virtually all the foods measured by this method were significantly lower than 6.25, including dairy proteins. Thus, while the currently commonly used 6.25 NCF may be erroneous, it is erroneous for **all** proteins. In fact, this has been noted by the Agence Française de Securite Sanitaire des Aliments in 2007[44] and Marriotti, et al., 2008[17] and a ***corrected default value for <u>all</u> proteins of 5.6 was proposed by both reports.***

The Kjeldahl method, the modified Kjeldahl method, and the combustion methods continue to be widely used for analytical measurement of protein. Direct analysis of amino acids to quantitate protein content in foods provides more accurate and nutritionally relevant values and this method of calculating protein content has been proposed by a number of organizations, the FAO[24], The EU Commission Scientifiec Committee on Food[4], and the Agence Française de Sécurité des Aliments[44]. We believe devoting time and resources to validating consensus methods for the direct measurement of protein, such as amino acid analysis discussed in FAO Report on Food Energy – Methods of Analysis and Conversion Factors[24] or by alternate methods that are being evaluated[46], and the dissemination of these data for public use would be more aligned with the Codex Alimentarius Commission's Procedural Manual[47] on determining priorities and initiating new work than initiating work to determine the "precise" NCFs for widely consumed proteins.

<u>4. POTENTIAL IMPACT OF CHANGING SOY NCF FROM 6.25 TO 5.71</u>

A nitrogen conversion factor of 5.71 for soy protein is based on outdated and inaccurate data originally reported in 1931. These data have since been discredited with improvements in analytical methods and technology, as well as an increased understanding of the chemical composition of proteins and the effects of amino acids and protein on human health. This will be described in detail in Section 5.

Changing the nitrogen conversion factor for soy protein from 6.25 to 5.71 would represent a departure from internationally recognized analytical methods, established nutrition clinical research procedures, as well as widely embraced trade and regulatory practices. Changing from the 6.25 to 5.71 conversion factor would result in an almost 10% reduction in the calculated protein content without any change to the product itself. Potential impacts would include:

- Elimination of isolated soy protein isolate as an ingredient used by infant and follow-up food manufacturers as it would be impossible to meet the product standard 90% protein minimum using a 5.71 nitrogen to protein conversion factor
- Significant costs to food manufacturers due to expensive label changes
    - "Isolated soy protein" would have to be removed from product ingredient lists
    - Changes to protein nutrition labeling
    - Potential requirement for product formula changes
- Confusion for food manufacturers seeking to make products containing isolated soy protein
- Confusion for consumers seeking products containing isolated soy protein
- Impacts on interpretation of data from decades of human and animal nutritional research for both scientific and lay audiences (which have generally used 6.25 as the NCF for soy protein)
- Trade and product labeling logistical difficulties presented with multiple and/or regionally implemented nitrogen conversion factors for follow-up formulae

<u>5. BACKGROUND RÉSUMÉ ON THE SCIENTIFIC BASIS FOR A NCF OF 6.25 FOR SOY</u>

As indicated previously, claims to change the NCF for soy from 6.25 to 5.71 are based on outdated and inaccurate data originally reported in 1931 by D.B. Jones, a USDA researcher[48]. These data were based on the 1898 publication of Osborne and Campbell[49] whose report did not claim that their values represented the nitrogen content of the whole bean, merely the fraction that they isolated. The Jones' factor of 5.71 has been disputed by other researchers who cite improvements in analytical methods and technology[4, 44,45, 50], as well as an increased understanding of the chemical composition of proteins[51-54,] and the effects of amino acids and protein on human health. Changing the NCF for soy protein from 6.25 to 5.71 will represent a departure from internationally recognized analytical methods, established

nutrition clinical research procedures, as well as widely embraced trade and regulatory practices. This position document will provide support from three different scientific frames of reference to substantiate our claim that a 6.25 NCF for soy should be retained for all soy protein-containing foods:

i. Published literature on proposed approaches to calculating NCFs

ii. Human nutrition studies assessing a source of protein's impact on human health

iii. The scientific analytical environment

Published literature on proposed approaches to calculating NCFs

A review of published literature exploring approaches to calculating NCFs was published in 2006 by the International Dairy Federation[55]. An updated version of the 2006 review by the International Dairy Federation was published in 2016 [56] with a focus on soy protein but with little new data. The papers cited in these reviews and summarized in Table 3, present inconsistent outcomes, highlighting the uncertainties with trying to establish a "precise" NCF for any protein. Many of the papers do not deal with the issue of non-protein nitrogen, which is present in both soy and dairy proteins to varying degrees. Furthermore, investigators disagree as to what constitutes non-protein nitrogen. Some investigators believe that amino acids and peptides account for non-protein nitrogen[57] while others believe these should be considered as part of the protein content since the purpose of the developing these calculations are for nutritive purposes and all organisms utilize proteins in their hydrolyzed form of amino acids and peptides[45,58].

Table 3. Publications on Methods to Calculate Nitrogen Conversion Factors

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
Osborne TB and Campbell GF (1898) J Am Chem Soc 20: 419-428[49]	Soy (*Glycine hispida*)	This paper did not propose a N to P conversion factor	17.5%	The authors of this paper did not claim that their values of %N represented the nitrogen content of the whole soybean, merely the fraction(s) that they separated; the authors claimed that glycinin was the major protein in the soybean but did not state the percent of glycinin typically found in soybeans Although not specifically cited by Jones, 1941[6] it is evident that Jones used this paper to arrive at the 5.71 NCF for soy
Jones DB (1941) United States Department of Agriculture, Circular No.183 (Original version 1931)[48]	Soy (*Glycine max*)	5.71	17.51	This citation bases the NCF for soy protein on the nitrogen content of only one of the storage proteins (glycinin),presumably based on the 1898[7] report above While citing 5.71 for soy protein, the Jones paper does not provide any data to show how this calculation was derived; only 1 sentence in the report is dedicated to soy protein The NCF for other crops is discussed in more detail but the 2006 IDF report[20] does not cite the Jones paper for the following crops: wheat (5.83), rye (5.83), barley (5.83) or oats (5.83)
Tkachuk R (1969) Cereal Chem 46: 419-423[58]	Defatted soybean	5.69		This paper derives NCFs for cereals and oilseeds based on data published in an earlier publication (Tkachuk, 1969 Cereal Chem 46: 206-218[59]) and derives glutamine and asparagine values from the content of ammonia (assumes all ammonia is derived from these 2 amino acids and simply divides the total ammonia by 2 and assigns the resultant values to asparagine and glutamine); this is based on Tkachuk's 1966 work in wheat (Tkachuk, 1966 Cereal Chem 43: 207-222[60]) where glutamine and asparagine values are directly measured by comparing enzymatically digested protein to

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
				acid hydrolyzed wheat protein; it is on this work *alone* in wheat that the assumption that free ammonia only comes from asparagine and glutamine; note that in the work on wheat, accurate estimates of the relative proportions of asparagine or glutamine were possible by direct measurement; errors would have resulted in NCF if one assumed equal proportions of both amino acids as subsequent investigators have done who cite this method Note also that this paper the author points out the errors and assumptions made in the Jones 1941[48] paper (i.e. not accounting for non-protein nitrogen), calling into question the NCF proposed by Jones[48]
DeRham O (1982) Lebensm. Wiss. Technol 15, 226-231[61]	Soy Isolate Soy (*Glycine max*)	5.6-5.8 5.75-5.8	17.54 17.24	DeRham points out that amino acid analytic methods do not routinely measure asparagine and glutamine, so in his analysis he ***assumed*** 50:50 or 75:25 amide:acid ratios when calculating the conversion factors from the listing of amino acid compositions of food in the FAO 1970 report[62] Soy protein has a ratio closer to 25:75 which would raise the calculated conversion factor from what deRham actually calculated DeRham points out that other investigators may have used different assumptions of amide:acid ratios (e.g. Jones 1941[48] and Morr 1981[52]) which may explain why conversion values in his report differ from those DeRham also questions Jones' stated values (Jones 1941[48]) and mentions that Jones used an arbitrary method to establish some of the conversion factors; DeRham also suggests that there are some errors in the Jones report, e.g. deRham suggests the conversion values reported in Jones 1941[48] for wheat flour and wheat bran should be inverted DeRham concludes his paper by saying that nutritional studies should continue to use the traditional 6.25 conversion factor until more precise conversion factors are available
Morr CV (1982) J Food Sci 47, 1751[63]	Soy (*Glycine max*)	5.76	17.36	Morr's 1982 paper is a follow-up of his 1981 paper (Morr, 1981 J Food Sci 46, 1362[52]) in response to personal communications Morr received from Posati and de Rham; the follow-up paper was to try to "minimize the magnitude of the discrepancies within the N conversion factors" determined by the Kjeldahl method and Factor Method (the latter was proposed by Morr, 1981[52] and involves calculating the NCF based on residual weights of amino acids determined by amino acid analyses) The 1981[52] paper states that the Factor Method is "recommended to provide the most accurate conversion factor". In that paper, Morr calculates an average NCF of 6.77 and 5.93 for 4 different soy protein preparations analyzed

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
				using the Factor Method and Kjeldahl Methods, respectively; calculations for 4 soy proteins whose compositions had been published previously averaged 6.58 In the 1982 paper[63] cited in the 2006 IDF report[55], Morr *uses the same amino acid compositional data* he derived in the 1981[52] paper for 2 soy protein preparations, but then "computes" the asparagine and glutamine contents according to the method of Tkachuk 1966[60], 1969[59]; meaning that the content of ammonia was used to *derive* the values for asparagine and glutamine based on the assumption that only these amino acids give rise to the ammonia; the total mole content of ammonia is subtracted from the total moles of asparagine and glutamine to *derive* the value of the carboxylic acid forms of these amino acids which are assumed to be in equal proportion Thus, values for asparagine and glutamine are not consistent with currently known relative proportions of glutamine and asparagine in soy protein
Boisen S, Bech-Andersen S and Eggum BO (1987) Acta Agric Scan 37, 299-304[64]	Soy Meal Soy Meal Soy Meal	6.30 (No Amides) 5.65 (With Amides) 5.49	15.87 17.7 18.21	NCFs calculated by even a single research group for a single sample can vary significantly (5.49 to 6.30 for soy meal) and 3 different factors are quoted in this report Note that the 2006 IDF report[55] cites this same paper to support a conversion factor range of 6.34 to 6.38 for milk and milk products; this citation provides three different skim milk powder conversion factors: 5.75, 6.13 (corrected for amides) and 6.9; ***The first two factors clearly are not in line with supporting a 6.34-6.38 conversion factor for milk and again demonstrate the problem with consistency in calculation and potential application of different NCFs*** As for the three NCFs provided for soy, 6.3 was calculated based on amino acid composition and protein nitrogen, 5.65 was calculated based on indirect and inaccurate estimates of amidation (measures of ammonia release after acid hydrolysis and *the assumption that all of the ammonia came from asparagine and glutamine*) and 5.49 was calculated based on amino acid nitrogen over total nitrogen, which always gives the lowest value (e.g. 5.75 for skim milk powder using this method)
Mosse J (1990) J Agric Food Chem 38, 18-24[65]	Soy (*Glycine max*) Soy (*Glycine max*)	5.38-5.67 5.76	18.18 17.36	The objective of this paper was "to show that in the absence of perfectly accurate values of the conversion factor, it is still possible to accurately determine its upper and lower limits" Mosse questions Jones ,1941 paper[48] by stating "...so that the questionable values he suggested remain still widespread today, in spite of various improvements successively made by Heathcote (1950), Kutscher and

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
				Langnau (1965), Tkachuk (1966a,b, 1969, 1977), Tkachuk and Irvine (1969), Ewart (1967), Holt and Sosulski (1979), Sosulski and Holt (1980) and Morr (1981, 1982)". Mosse provides a detailed mathematical approach to determining NCFs (3 possible values k_A k_P and k, depending on calculation method) for 10 cereals and 6 legumes/ oilseeds and shows that the conversion factors that he calculates based on residual amino acids weights change as the nitrogen contents of the samples increased (not always in the same direction depending on the sample type) *providing more evidence for the difficulty in calculating and assuring that analysts use appropriate accurate nitrogen to protein conversion factors* Mosse also pointed out that other researchers have provided NCFs that were in error if they omitted to correct for the amide nitrogen values (coming from asparagine and glutamine); however, his corrections (calculations for k_A) were based on measures of ammonia release after acid hydrolysis and *were based on the assumption that all of the ammonia came from these 2 amino acids only* Mosse's earlier paper (Mosse, 1985 J Cereal Sci 3: 115-130[66]) in wheat cites Tkachuk, 1969[59] as being the only published literature to indicate that all NH3 comes from Gln and Asn alone, however only wheat, not soy, was studied by Tkachuk Despite Mosse's claim in current paper that "...the AA compositions used here probably represent the most complete analyses of the total proteins of cultivated seeds" *no amino acid data are provided in the paper, appendices or supplemental data, so the reader is not able to replicate or verify the calculations made in the paper* Amino acid data for non-soy proteins are available (other published papers), *but the data used for soy protein in this paper are "unpublished" and unavailable to view*
Sosulski FW and Holt NW (1980) Can J Plant Sci 60: 1327-1331[67]	Soybean	5.58		In this paper only NCFs for grain legumes were calculated exactly as per Tkachuk, 1969[58] using amino acid analyses; thus one would expect similar values to those Tkachuk reported It should be noted that using the SAME METHODS, Sosulski and Imafidon (Sosulski and Imafidon, 1990 J Ag Food Chem 38: 1351-1356[68]) reported NCFs of 6.02 to 6.15 for dairy products and 5.61 to 5.93 for egg, meat and fish products
Marriotti F et al. (2008) Crit Rev Food Sci	Soybean	5.5		This paper is a review of the issues in calculating NCFs and argues that an NCF of

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
Nutr 48: 177-184[45]				6.25 is incorrect for **all** major human dietary protein Authors admit addressing this issue has been avoided "because scientists fear opening the Pandora's box" Marriotti et al point out the flaws with the Jones factors (Jones, 1941[48]) were due to assumptions made and the technology available in 1941 and that amino acid analyses are the preferred method to calculate NCFs, when other additional factors are also taken into account (e.g. non-protein nitrogen). With regard to concerns that amino acid measures have an inherent increased variability compared with measures of nitrogen, Marriotti, et al. point out that the variability of amino acid measures would not significantly impact NCF measures (calculated CV of 2%) and that improvements in amino acid analyses are occurring An interesting point raised by Marriotti, et al. that warrants consideration, is that for proteins with a lower NCF than 6.25, measures of protein content decrease WHILE THE CHEMICAL SCORE (PROTEIN QUALITY) increases (compared to proteins with higher NCFs); example calculations show that more amino acids to meet nutritional requirements are provided in less protein for the protein with lower NCF
Sriperm N et al. (2011) J Sci Food Agric 91: 1182-1186[69]	Soy meal	5.64		The purpose of this paper was to get to specific NCFs for feedstuffs "to minimize the feeding of excess nitrogen (N) and to reduce N pollution". Calculations were based on the methods reported by Mosse, 1990[65] so not surprising that soy meal NCF was similar to that of Mosse Interestingly, if the purpose of the paper was to get to specific NCFs to reduce feeding excess N, then one must consider how this information will be used; if the currently used NCF of 6.25 for soy meal in feed is reduced to 5.64, does the feed formulator add more soy meal to get to the required protein levels and potentially harm the environment by increasing the excreted N in feces? OR should all the existing requirements be lowered in view of the fact that all protein content in feedstuffs, previously based on a NCF of 6.25, should be now considered lower by 5.64/6.25 (reduction of 10%). If the latter, then there would be NO CHANGE to actual formulations *per se* but this would require a costly paper exercise to change the nutritional composition and labels for protein.

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
Maubois J-L and Lorient D (2016) Dairy Sci and Technol 96, 15-25[57]	Soy (*Glycine max*)	5.61-5.79		This paper, published in a journal devoted to dairy research, is a review that attempts to provide a scientific basis for the nitrogen to protein conversion factors of 6.38 for cow milk protein and 5.71 for soy protein but does not provide primary data to support these NCFs The authors point out the difficulty in obtaining accurate or 'true' nitrogen to protein conversion (NCF) factors; they point out that "…scientists have turned to determining the NCF from the amino acid composition" Interestingly these authors consider low molecular weight peptides and free amino acids as non-protein nitrogen (NPN) but in an earlier paper Mariotti, et al.[45] indicate that there are different objectives when using a NCF and for nutritional considerations all amino acids should be considered in the NCF; this further points out the controversies that arise when using NCFs in general Maubois and Lorient propose that the amino acid sequence of proteins or primary structure of proteins be used to calculate the NCF; this requires a thorough knowledge of the primary structure of proteins which is NOT available for most proteins, but is available for milk proteins; while the major soy protein sequences are known, the overall number of proteins contributing to total protein from soybean[70] is higher than that of milk protein[71] ; therefore it is unlikely that this method would offer any advantages as the relative amounts of the different proteins would need to be known with some certainty and assumed not to change with different lots of protein to develop an accurate NCF This paper cites Utsumi, 1992[72] as being the source of the sequence data on which the calculations of the soy proteins b-conglycinin and glycinin NCF shown in Table 3 are based; Utsumi, 1992[72] does not provide direct sequence data but Utsumi, 1997[73] does provide sequences for these 2 proteins only; since the sequences are listed for the different subunits and their ratios vary, it is not clear how the NCFs were calculated by the authors (this is not shown); if one uses the amino acid compositions of b-conglycinin[74] and glycinin[75] to calculate the NCF (using residual weights of the amino acids and weight of nitrogen) for these subunits one obtains 6.31 and 6.36, respectively Similarly when Maubois and Lorient attempt to calculate the soy protein NCF based on relative ratios of b-conglycinin (7S) to glycinin (11S) and the latters' respective sequences , they do not provide a clear explanation as to how the NCFs are calculated and how they take into

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
				account soy hemagglutinin and 7S glycosylation Maubois and Lorient also have a section in the paper on "Processing and anti-nutritional factors" which are not related to the topic of nitrogen to protein conversion factors; this section is simply added to discount soy protein as a high quality protein for infant formulas and cites very outdated publications and information With regards to suitability for infant formula, the authors attempt to make a case that soy protein is not suitable for infant formula; their unsubstantiated arguments are meaningless in view of the data emerging from the laboratory of Dr. Tom Badger and his Beginnings Study which are summarized in Table 4 and show that soy protein based formulas promote normal growth and development comparable to cow milk based formulas[76-78]. A recent meta-analysis by Vandenplas et al.[79] also confirms the safety and normal growth promoting properties of soy-based infant formulas. Authors also claim that proposal to use 6.25 NCF for soy protein is unacceptable because it forgets the enormous work conducted over the past 50 years; the same can be said for the Jones' factor of 5.71 for soy protein which is still quoted for more than 50 years despite it being based on a faulty logic

Human nutrition studies assessing a source of protein's impact on human health

Human nutrition research continues to demonstrate that soy is a high-quality protein that supports growth and maintenance when consumed as a sole source protein. Historically, 6.25 has been used as the NCF for soy for calculate the protein content of diets in infant and adult human clinical studies. A brief summary of some key studies and meta-analyses is provided in Table 4.

Table 4. Human Nutrition Studies Assessing Impact of Dietary Soy Protein on Health Outcomes

Citation	Product Name/ Class	NCF used for soy protein	Type of Study & Subjects	Comments
Rand WM et al. (2003) Am J Clin Nutr 77: 109-127[80]	Soy protein	6.25	Meta-Analysis of Nitrogen Balance studies in Adults	This meta-analysis was conducted in response to a request from the FAO/WHO/UNU to assess the protein requirements in healthy adults and tested a variety of animal or plant-based proteins or mixtures of these Protein requirement in adults defined as "the continuing intake of dietary protein that is sufficient to achieve body nitrogen equilibrium (zero balance)" Despite the known limitations of N balance studies, this method remains the primary approach for determining protein requirement in adults because there is no validated or accepted alternative

				Studies tested soy protein (7 as sole source and 2 as mixed sources) using an NCF of 6.25 as the basis for determining the quantity of protein intake There were various factors that contributed to the variability in N balance response due to differences in studies, differences between subjects and day to day differences within subjects; however, there was no significant difference between studies based on whether the dietary protein was predominantly from animal, vegetable or mixed-protein sources For the soy studies, the authors concluded: "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)" The major source of dietary protein was found to have an insignificant effect on the median requirement, slope or intercept for N balance versus N intake plots One would expect that if the NCF of 6.25 applied to each of the studies led to an overestimation of the actual protein intake, ***then one would expect a lower N balance in the soy protein studies, but this was not observed*** Thus, it can be concluded from these studies that the use of a NCF of 6.25 for soy does not lead to erroneous estimations of protein requirements
Jing H et al. (2010) Early Hum Devel 86: 199-125[76]	Soy protein	6.25	Infant Formula Study to assess effects of breastmilk compared with formula feeding on brain activity in developing infants	Development of brain activity during infancy differs between those who are breastfed compared to with those fed either cow milk or soy protein-based formula, but was generally similar for the formula-fed infants
Andres A et al. (2013) J Pediatr 163: 49-54[77]	Soy protein	6.25	Infant formula study to assess effects of breastmilk compared with formula feeding on body compositio n and bone mineral	Anthropometric data were similar in soy-formula-fed and cow milk-formula-fed infants; however soy-fed infants were significantly leaner with greater fat-free mass compared with cow-milk formula-fed and breast-fed infants during the first 6 months of life Bone mineral content (BMC) was higher in breast-fed infants compared with cow-milk or soy-formula-fed infants at 3 months, but by age 9 and 12 months BMC was higher in cow-milk and soy-formula-fed infants, with the highest bone mineral accretion occurring in the cow-milk formula fed group

			content in developing infants	
Pivik RT et al. (2013) Intl J Psychophysiol 90: 311-320[78]	Soy protein	6.25	Infant formula study to assess effects of breastmilk compared with formula feeding on cardiovascular development in infants	Although subtle effects of diet and gender were observed, there were no atypical findings with regard to cardiovascular development Differences observed were generally greater between breast-fed and formula-fed groups than between formula-fed infants
Vandenplas Y et al. (2014) Br J Nutr 111: 1340-1360[79]	Soy protein	6.25	Meta-Analysis of Soy Infant formula studies	This is a meta-analysis that reviews the safety of soy infant formula in relation to anthropometric growth, bone health (bone mineral content), immunity, cognition and reproductive and endocrine functions using studies published from 1909 to 2013 The authors concluded that "the patterns of growth, bone health and metabolic, reproductive, endocrine, immune and neurological functions (for soy-based infant formula) are similar to those observed in children fed cow milk-based formula and human milk"

The studies summarized in Table 4 indicate that the intake of soy protein, when based on a NCF of 6.25, resulted in similar nitrogen balance in adults and similar growth and development of infants when compared to animal and dairy protein. It is worthy to consider how these results may be interpreted should the NCF of soy protein be changed from 6.25 to 5.71. It could then be considered retrospectively, that 9% less soy protein resulted in similar nitrogen balance and similar infant growth characteristics to that observed with milk protein. Another consideration may be that changing the NCF for soy protein to 5.71 would require reformulating the infant formula to contain more soy protein by weight to meet the infant formula protein requirements. However, that could meet with considerable resistance, since there is a growing body of data that suggest that high dietary protein intakes in infancy and in growing children can induce adverse effects on the risk of obesity and associated diseases[81]. As indicated earlier recent recommendations to reduce the protein content for infants and follow-up formula by the FDA in the USA[6] and similar recent recommendations published by an international expert panel of pediatric nutritionists[7] are based on the emerging data suggesting possible adverse effects of too much protein consumption in early life. In fact, in their "Review of the Standard for Follow-up Formula (CODEX STAN 156-1987)" the electronic working group also stated there was "widespread support in the eWG for the establishing a minimum protein level of 1.8 g/100 kcal…This level is aligned with the Infant Formula Standard and the recently revised EU regulation and signifies a marked decrease in the protein content compared to current requirements for follow-up formula (minimum of 3.0 g/100kcal)".

Data supporting a lower protein intake in infants has been provided by a multicenter European study where over a thousand healthy term infants were randomly assigned to receive cow milk-based formulas and follow-on formulas with lower (1.77 and 2.2 g protein/100 kcal, respectively) or higher (2.9 and 4.4 g protein/100 kcal, respectively) protein levels[82]. At 2 years of age, the adjusted *z* score for weight-for-length was found to be 0.20 greater (P = 0.005) in the higher- than in the lower-protein formula group[82] and in a follow up of these children at 6 years of age, the high protein group had a significantly higher BMI (by 0.51, P = 0.009) compared to the low protein group[83]. The study investigators also demonstrated that long-term mental performance of children on the low protein intervention was unimpaired compared to the high protein intervention[84] allaying any concerns that reducing protein intake in infancy would have led to any adverse developmental effects. This and other studies then

indicate that lowering protein intake in infants, rather than raising protein intake levels, would be associated with a reduced rate of obesity.

Use of the 5.71 factor instead of 6.25 in the calculation of protein content for soy-based follow-up formula could result in excessive protein intake. If grams of protein for a follow-up formula are calculated using a 5.71 nitrogen to protein conversion factor are compared to what the gram amount would be using a 6.25 conversion factor, the protein range would actually be 3.28 – 6.01 g per 100 kcal of FUF (assumes 9.2% reduction in protein content with use of 5.71 vs 6.25), instead of the 3 – 5.5 g/100 kcal range that is currently listed in the Codex FUF Standard[85].

Table 5. Follow Up Formula Calculations: Protein content using 5.71 vs. 6.25

	Protein Isolate to be Added	
N Conversion Factor	**3 g protein/100 kcal**	**5.5 g protein/100 kcal**
6.25	3 g	5.5 g
5.71	3.28 g	6.01 g

In the US FDA revised nutrition and supplement facts labels and rules for serving sizes published in May 2016[6]. The RDI for protein for infants was reduced from 14 g/day to 11 g/day and for children 1-3 years of age the DRV was reduced from 16 g/day to 13 g/day[6]. Changing the conversion factor for soy from 6.25 to 5.71 would require adding more soy protein to food products, counter to the most recent scientifically driven trends in regulatory nutrition recommendations.

Another argument for the lack of utility of specific NCFs is based on the observations of Heidelbaugh ND et al.[86] who showed that variations in calculating the protein content of adult menus or diets using different NCFs derived by different methods, minimally affect the values obtained for total protein contents, since any errors resulting from using 6.25 or specific NCF factors (e.g. Jones' factors) tend to be randomly distributed among any variety of foods when an overall menu containing healthy foods is analyzed. Heidelbaugh ND et al. (1975)[86] demonstrated that the protein content of menus designed for Skylab astronauts, which consisted of 68 different foods, differed by less than 3% when calculated using a NCF of 6.25, using Jones' factors or using derived NCFs based on amino acid composition of the foods. Therefore, it is reasonable to conclude that for human diets that contain a variety of healthy foods, there is no need, based on nutritional considerations, for efforts to be expended on developing specific NCFs to calculate protein content for individual foods.

The scientific analytical environment

a. Analytical Methods Support a 6.25 Conversion Factor

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. It should be noted that Wolf, et al.[86] reported on the nitrogen content of soybean protein and several fractions of these proteins along with purified proteins. These preparations contained from 16.2 to 16.51% nitrogen[86] (NCF would be 6.05 to 6.17). Wolf, et al.[87] reported that a cold insoluble fraction contained 17.46% nitrogen which was probably very similar to the soy sub-fraction used by Osborne and Campbell in their measures[49], which is the citation that Jones used to support an NCF of 5.71 for soy.

By way of comparison, the NCF for dairy has been based on the nitrogen content of acid-precipitated casein published in a report in 1883 by Hammarsten[88] which was found to be 15.67% (NCF = 6.38). This is also the citation used by the IDF to support an NCF of 6.38 for dairy in their recent Bulletin[56] despite the fact that dairy protein contains whey and other proteins that individually vary in their NCF values[89].

b. Newer Protein Analysis Methods Provide More Accurate Protein Data and Demonstrate that a NCF of 5.71 for Soy is Incorrect

The 5.71 nitrogen conversion factor for soy protein is based on analytical data generated by D.B. Jones, Principal Chemist of the United States Department of Agriculture (USDA) in a Circular (1931, slightly revised 1941)[48]. In this Circular[48], 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. He also reported a wide variation in the nitrogen content across these protein sources. Jones justified the 5.71 factor for soybeans by stating 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). This 5.71 conversion factor for soy protein, based on Jones' logic, is false and many subsequent publications have repudiated the 5.71 NCF for soy[44,45,59,61,65].

A NCF for based of 5.71 as Jones calculated is incorrect as research[51, 53,54] has shown that there can be wide variations in the levels of the major proteins in soybeans, glycinin and ß-conglycinin, which could result in widely different nitrogen conversion factors if Jones' logic were carried out. Murphy and Resurreccion (1984)[51] found glycinin/ß-conglycinin ratios varied significantly, depending on the soybean variety and differences in seasonal growing conditions. Roberts and Briggs (1965)[53] and Koshiyama (1968)[54] found that soy proteins typically consist of about 35% ß-conglycinin and contain between 15.5%[9] - 15.9%[10] nitrogen, respectively, translating to a conversion factor of 6.45 – 6.29. Utsumi et al.[73] reported that the ratio of 11S to 7S globulins in soybean cultivars varies from 0.5 – 1.7, making it apparent that the concept of a single specific and accurate NCF for soy would be difficult to know with any confidence. This is true for any naturally occurring protein ingredient, including milk protein, which can show variations in composition[90].

In recognition of the inconsistencies and inaccuracies inherent in analytical methods that measure protein indirectly through nitrogen content, other methods for measuring protein have been developed. In December of 2002, FAO convened the "Technical Workshop on Food Energy: Methods of Analysis and Conversion Factors". Outcomes of this workshop were published in FAO Food and Nutrition Paper 77[24]. One of the significant outcomes of this workshop was the recommendation by the expert panel for a superior and more accurate method using the sum of the anhydrous amino acids to measure protein. That is: ***"****To measure protein as the sum of individual anhydrous amino acids, rather than the measurement of nitrogen by the Kjeldahl and other indirect methods*".

Further, the workshop participants recommended that food composition tables should express protein content by the sum of anhydrous amino acids whenever possible, so these data may be used globally[24]. Using this recommended method, analytical product data supports a 6.25 nitrogen conversion factor as discussed below.

c. Analytical Product Data Using FAO's 2003 Recommendation

The FAO Food and Nutrition Paper 77[24] recommended protein measurement by amino acid analyses. Heidelbaugh et al.[86] also proposed that the most accurate way to calculate NCFs for dietary purposes was based on amino acid composition. This method has been used by others to calculate NCFs for algae[39] and fish[91] in recent studies. If one applies this method to calculating the nitrogen conversion factors for defatted soybean meal, soy protein concentrate, and isolated soy protein one obtains values that range from 6.24 – 6.37 (Tables 6-8). The amino acid content of various soy ingredients produced from 1993-2007 were measured using the method described in Angell et al.[39] and Diniz et al.[91]. The anhydrous amino acid content was calculated as the amino acid molecular mass minus the molecular weight of water.

In addition, application of the FAO method to isolated soy protein amino acid data from 1982, isolated soy protein data currently available on the USDA National Nutrient Database for Standard Reference[92], and to amino acid data independently published in the scientific literature by Morr, 1981[52] yield a 6.30-6.31 conversion factor for soy protein. Application of the FAO method to amino acid values to commonly consumed foods, like soymilk[93] and tofu[94], published in the USDA National Nutrient Database for Standard Reference yields a 6.30 conversion factor. The USDA National Nutrient Database for Standard Reference lists these with an NCF of 6.25 using the approved AOCS and AOAC standards listed in Table 2.

The nitrogen conversion factors calculated using data from a fifteen-year span of amino acid data demonstrate an overall average value of 6.33 (Tables 6-8). These were calculated based on amino acid analyses were performed on 55 soy protein samples (flakes and flour, isolated soy protein (ISP) or soy protein concentrates (SPC) according to conventional methods[95]. Samples were subject to acid

hydrolysis at 110°C for 24 hours and the amino acids were separated by ion exchange chromatography and detected with ninhydrin. Each amino acid was quantitated against a standard known concentration for aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, methionine, isoleucine, leucine, tyrosine, phenylalanine, histidine, lysine and arginine. Methionine and cysteine were also quantitated after performic acid oxidation and tryptophan was quantitated after sodium hydroxide hydrolysis[95]. Values for amino acid weights were used to calculate a nitrogen conversion factor essentially as described by Angell et al.[39] and Diniz et al.[91].

With the exception of one data point at 6.24 for one lot of defatted soy meal, the remaining nitrogen conversion factor values vary from 6.29 – 6.37. It is well recognized by experts in the field that plant products exhibit natural year-to-year differences and product-to-product differences, which are to be expected due to different growing conditions and variations in manufacturing processes. The data for isolated soy protein ingredients presented in this document demonstrate stability of the protein nitrogen conversion factor over a 15-year period of time (Tables 6-8).

The data in Tables 6-8 are based on analytical data from daily production samples analyzed by a single independent laboratory and show a nitrogen to protein ratio that is greater than the value, 6.25. Amino acid data used to calculate values for NCF of Isolated Soy Protein (2004-2007), soy protein concentrate, and soy flakes shown in Tables 6, 7, and 8, respectively, can be found in Appendix Tables 1-3. Very importantly, it is noteworthy that these data are much more consistent with a nitrogen conversion factor of 6.25 than 5.71.

Table 6. 1993-2007 Isolated Soy Protein Industry Data*, **

Year	N Conversion Factor
1993	6.31
1994	6.33
1994	6.31
1995	6.33
1995	6.32
1997	6.35
1997	6.34
1998	6.36
1998	6.36
2002	6.33
2002	6.33
2002	6.32
2002	6.33
2003	6.34
2003	6.35
2004	6.35
2004	6.33
2004	6.36
2004	6.34
2004	6.34
2005	6.36
2005	6.35
2005	6.37
2005	6.34

2006	6.31
2006	6.35
2006	6.36
2006	6.34
2006	6.36
2006	6.33
2006	6.36
2007	6.31
2007	6.30
2007	6.31
2007	6.32
Mean	**6.34**
Standard Deviation	**0.02**

*Analytical method adapted from original method of Morr, 1981[52] and as described in Angell et al.[39] and Diniz et al.[91]

** Data provided by DuPont (St. Louis, MO); Analyses conducted at NPAL Analytical Laboratories (St. Louis, MO, USA)

Table 7. 2004-2007 DuPont Soy Protein Concentrate Product Data*, **

Year	N Conversion Factor
2004	6.31
2004	6.29
2004	6.34
2004	6.32
2005	6.35
2005	6.37
2005	6.32
2006	6.32
2006	6.32
2007	6.29
Mean	**6.32**
Standard Deviation	**0.03**

*Analytical method adapted from original method of Morr, 1981[52] and as described in Angell et al.[39] and Diniz et al.[91]

** Data provided by DuPont (St. Louis, MO); Analyses conducted at NPAL Analytical Laboratories (St. Louis, MO, USA)

Table 8. 2005-2007 DuPont Soy Flake & Flour Product Data*, **

Year	N Conversion Factor
2005	6.30
2005	6.31
2005	6.31

2004	6.34
2005	6.31
2005	6.32
2005	6.31
2005	6.24
2006	6.31
2007	6.29
Mean	**6.30**
Standard Deviation	**0.03**

*Analytical method adapted from original method of Morr, 1981[52] and as described in Angell et al.[39] and Diniz et al.[91]

** Data provided by DuPont (St. Louis, MO); Analyses conducted at NPAL Analytical Laboratories (St. Louis, MO, USA)

d. General Notes on Amino Acid Analyses

In order to perform amino acid analysis on intact protein, it is necessary to release the constituent amino acids using hydrolysis. This is most commonly done via acid hydrolysis in 6N HCl over a period of time. Acid hydrolysis results in the conversion of amidated amino acids (glutamine and asparagine) to their acidic counterparts (aspartate and glutamate). Thus, during analysis, glutamine and glutamate are quantitated together, as are asparagine and aspartate. Since the amidated amino acids contain two nitrogen molecules and the acidic forms one, one cannot accurately calculate a NCF using amino acid analysis data alone, since one cannot accurately determine amidated amino acid content.

There is currently no method for direct quantitation of both glutamine and asparagine from protein. In 1966, Tkachuk[60] described two separate methods for estimating the amounts of amidated amino acids in protein samples. In the first method, amide ammonia released during hydrolysis is measured at several time points, then extrapolated to zero to estimate the concentration of amidated amino acids present in the starting sample. This method assumes linearity throughout the hydrolysis process, and is an extrapolation from only three time points. In 1982, Morr[63] published a research note in which he recalculated nitrogen conversion factors for soy products using the ammonia estimation method of Tkachuk[58]. In this note, Morr reduced the factors to 5.66-5.79 for four soy products based on an estimation of the amount of glutamine and asparagine present in each product[63]. Given that Tkachuk's method[60] is based on estimation of amide content in wheat, one cannot conclude that those factors calculated by Morr, 1982[63] are accurate.

In the second method referenced in Tkachuk, 1966[60], he attempts to determine amidated amino acid concentrations using three separate hydrolytic enzymes prepared in his laboratory using published methods. It should be noted that any side activities in these preparations had not been measured; it was assumed that no asparagine or glutamine deamidase activity was present that would lead to inaccurate results. In order to obtain concentrations for glutamine and asparagine, Tkachuk[60] performed both enzymatic and acid hydrolyses on samples, separated the resultant amino acids by chromatography, then compared the two chromatograms to determine differences. It should be noted that glutamine and asparagine were presumed by Tkachuk[60] to co-elute with serine (based on retention times measured using pure standards). Thus, he could only estimate the amount of each by measuring differences in the serine peak between acid hydrolyzed and enzymatically hydrolyzed samples. Direct measurement of asparagine and glutamine released by this method was not possible. In addition, amino acid recoveries using the enzymatic method were poor, reaching only approx. 80% compared to >90% for the acid hydrolysis method. Thus, although valiant, Tkachuk's second method[60] can only be viewed as means of approximating the levels of asparagine and glutamine present in intact proteins.

Recently, a method was published using derivatization with [bis(trifluoroacetoxy)iodo]benzene (BTI) to measure glutamine levels in intact proteins[96]. Under the appropriate conditions, this reagent converts bound glutamine to acid-stable L-2,4-diaminobutyric acid (DABA). Thus, one can quantitate glutamine by measuring the DABA released following acid hydrolysis. BTI also converts asparagine to L-2,3-diaminopropionic acid (DAPA). However, Kuhn, et al.[96] have reported poor recovery of DAPA upon hydrolysis, so were unable to use this method for asparagine quantitation.

In conclusion, use of the Morr Factor method[63] to determine NCFs from anhydrous amino acid data can only approximate the factor, because it is not currently possible to measure asparagine and glutamine concentrations using direct methods. Therefore, use of NCFs derived from amino acid analysis data can only be viewed as estimates, until such time when validated, quantitative methods for determination of all native amino acids present in a given sample are developed. Newer methods being developed for protein quality measurements are largely dependent on accurate measures of individual amino acids in dietary protein sources[97]. Therefore, there is promise that reliable and perhaps more cost-effective methods of amino acid analyses will soon be more readily available which can be used to directly measure protein content in foodstuffs, obviating the need for NCFs.

e. The 5.71 Conversion Factor for Soy does not Reconcile with Mass Balance Calculations

As part of a quality assurance program, soy protein ingredient manufacturers generally analyze protein, moisture, fat, and ash (proximates) for each lot of product. Proximates are measured by direct analysis. Carbohydrates are not directly analyzed. Carbohydrate values are calculated by difference[23]: 100 minus the sum of protein, moisture, fat, and ash. Therefore, proximates must always add up to 100%. Isolated soy protein typically contains <1% carbohydrate, as determined by calculation[23]. Typical proximate values (on dry matter basis) for isolated soy protein using 6.25 as the conversion factor generate proximate data that can be supported by direct analysis (Table 9). Typical values for isolated soy protein using 5.71 as the conversion factor, however, generate proximate data that cannot be supported by direct analysis (Table 10). Use of the 5.71 factor results in 8% "missing mass". This 8% fraction cannot be properly classified as a nutrient by analytical methods, as the proximate values do not add up to 100%.

Table 9. Using 6.25 NCF: Typical Macronutrient Data for Isolated Soy Protein

Macronutrient	**Typical Value**
Protein (dry matter basis)	91%
Fat	4%
Ash	4%
Carbohydrate	1%
Missing Mass	**0%**

Table 10. Using 5.71 NCF: Typical Macronutrient Data for Isolated Soy Protein

Macronutrient	**Typical Value**
Protein (dry matter basis)	83%
Fat	4%
Ash	4%
Carbohydrate	1%
Missing Mass	**8%**

6. FINAL SUMMARY AND RECOMMENDATIONS

This document has provided significant regulatory and scientific support for the use of 6.25 as the soy protein NCF and has also demonstrated the errors and potential unfortunate economic and nutrition and health consequences of changing the NCF for soy to 5.71. Therefore, with this large body of data, we propose the following three recommendations to the CCNFSDU with regard to Agenda Item 5 at the 5-9 December 2016 meeting:

1. We request that in the Codex standard on Follow-up Formula an NCF of 5.71 for soy should be removed from Footnote 2 in **section 3.2.3 (Protein)**. This can be accomplished by a) deleting the last sentence of the footnote, or b) at minimum, terminating the last sentence after the words "milk products". Although a NCF of 6.38 for milk products may not be warranted, the scope of this room document focused on the NCF for soy and provided data only in that respect. Examples of the revised footnote using the two proposed suggestions would then read:

    a. [2]For the purposes 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.

    b. [2]For the purposes 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.

2. If work by any scientific organization is initiated to develop scientifically based and validated methods to calculate specific NCFs for proteins, then the FAO should be asked to convene a panel to study the possible impact to infant and children's health if follow-up products are re-formulated taking into account new NCFs for soy or milk protein.

3. We would recommend that resources from CODEX committees or FAO/WHO be devoted to identifying accurate and cost-effective means of determining protein content of foods by direct measures of protein content, obviating the need for specific NCFs for all proteins. This has been recommended by the FAO and by numerous investigators and organizations cited in this room document. This is consistent with advancements in analytical testing technology and would enhance methods for improving food safety and quality.

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8. Appendix

Acronyms

AACC	AACC International (previously known as American Association of Cereal Chemists)
AOAC	AOAC International (previously known as Association of Official Analytical Chemists)
AOCS	American Oil Chemists Society
FAO	Food & Agriculture Organization of the United Nations

ISP	Isolated Soy Protein
ISO	International Organization for Standardization
SPC	Soy Protein Concentrate
USDA	United States Department of Agriculture
WHO	The World Health Organization

Appendix Table 1: Calculation of Nitrogen Conversion Factors for Soy Protein Isolate from anhydrous amino acid data

	g anhydrous AA residue/100 g sample																		
AA	**2004**	**2004**	**2004**	**2004**	**2005**	**2005**	**2005**	**2005**	**2006**	**2006**	**2006**	**2006**	**2006**	**2006**	**2007**	**2007**	**2007**	**2007**	**Averages**
lys	5.54	5.51	5.37	5.45	5.43	5.51	5.36	5.44	5.35	5.38	5.33	6.37	5.44	5.44	5.50	5.37	5.39	5.36	**5.47**
Hist	2.11	2.09	2.04	2.05	2.06	2.08	2.02	2.07	2.04	2.02	2.04	2.02	2.12	2.09	2.11	2.09	2.07	2.08	**2.07**
Arg	6.86	6.80	6.71	6.76	6.75	6.84	6.84	6.74	6.58	6.79	6.72	6.70	6.80	6.72	6.72	6.68	6.57	6.62	**6.73**
Asp	10.26	9.74	9.70	9.84	10.15	10.23	10.19	9.77	9.66	9.97	10.03	10.06	9.82	10.05	9.77	9.62	9.66	9.77	**9.90**
Thr	3.19	3.06	3.05	3.10	3.17	3.15	3.11	3.04	3.11	2.95	3.06	3.05	3.04	3.12	3.01	3.01	3.02	3.06	**3.07**
Ser	4.34	4.16	4.11	4.23	4.26	4.26	4.22	4.10	4.19	4.16	4.20	4.22	4.18	4.09	4.08	4.03	4.01	4.04	**4.16**
GlutA	18.29	18.10	17.90	18.12	18.41	18.74	18.67	18.21	16.25	18.63	18.17	17.91	19.21	18.38	16.73	16.42	16.45	16.45	**17.84**
Pro	4.36	4.77	4.48	4.40	4.54	4.49	4.50	4.48	4.60	4.58	4.73	4.55	4.64	4.79	4.50	4.50	4.33	4.45	**4.54**
Glyc	3.17	3.08	3.04	3.09	3.13	3.13	3.08	3.08	3.08	3.05	3.06	3.08	3.09	3.12	3.06	3.02	3.05	3.04	**3.08**
Ala	3.56	3.32	3.36	3.41	3.45	3.40	3.35	3.37	3.40	3.24	3.38	3.39	3.36	3.40	3.34	3.29	3.34	3.37	**3.37**
Cyst	1.03	1.14	1.06	1.05	1.08	1.05	1.08	1.03	1.08	1.11	1.06	0.99	1.02	1.05	1.03	1.06	1.02	1.05	**1.06**
Val	4.16	4.15	4.13	4.06	4.15	4.13	4.15	4.09	3.99	3.88	4.07	4.08	4.10	4.40	4.17	4.20	4.18	4.24	**4.13**
Meth	1.12	1.27	1.23	1.19	1.15	1.11	1.13	1.13	1.16	1.16	1.10	1.09	1.14	1.14	1.11	1.14	1.15	1.14	**1.15**
Isolu	3.98	3.73	3.74	3.79	3.87	3.82	3.87	3.74	3.74	3.76	3.89	3.94	3.78	3.93	3.87	3.83	3.81	3.91	**3.83**
Leu	7.20	6.77	6.83	6.93	6.94	6.89	6.92	6.75	6.85	6.68	6.97	7.08	6.90	6.88	6.77	6.70	6.75	6.84	**6.87**
Tyr	3.57	3.41	3.35	3.49	3.46	3.41	3.48	3.40	3.46	3.36	3.45	3.51	3.44	3.45	3.43	3.33	3.37	3.37	**3.43**
PhenylA	4.82	4.50	4.46	4.60	4.69	4.66	4.69	4.47	4.45	4.45	4.73	4.81	4.57	4.55	4.51	4.42	4.40	4.53	**4.57**
Trypto	1.09	1.11	1.14	1.09	1.06	1.07	1.02	1.07	1.09	1.06	1.07	1.05	1.05	1.12	0.99	1.09	1.12	1.11	**1.08**
g protein/100g sample	88.65	86.72	85.69	86.63	87.74	87.96	87.66	85.98	84.09	86.22	87.07	87.89	87.71	87.72	84.71	83.81	83.69	84.43	**86.36**
Total g N /100 g sample	13.96	13.69	13.52	13.65	13.8	13.85	13.77	13.57	13.32	13.58	13.68	13.87	13.79	13.8	13.43	13.3	13.26	13.36	**13.62**
NCF	6.35	6.33	6.34	6.35	6.36	6.35	6.37	6.34	6.31	6.35	6.37	6.34	6.36	6.36	6.31	6.30	6.31	6.32	**6.34**

Standard Amino Acid Analysis was performed as described in the text (see Section V above). Anhydrous amino acid weights were calculated by subtracting the MW of water (18 Da) from each amino acid, and the resultant weights tallied to determine percent protein content in a 100 gm sample. Total sample nitrogen was determined by tallying the N present in each AA residue based on percent nitrogen values. NCF was determined by dividing protein content by total nitrogen.

Appendix Table 2: Calculation of Nitrogen Conversion Factors for Soy Protein Concentrates from anhydrous amino acid data

	g anhydrous AA residue/100 g sample							
AA	**2004**	**2004**	**2004**	**2004**	**2005**	**2005**	**2005**	**Averages**
lys	5.59	5.52	5.58	5.60	5.51	5.54	5.51	**5.55**
Hist	2.14	2.10	2.09	2.10	2.09	2.07	2.11	**2.10**
NH#	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**
Arg	6.71	6.59	6.56	6.56	6.57	6.67	6.57	**6.61**
Asp	9.87	9.72	9.96	9.81	10.14	10.33	9.80	**9.95**
Thr	3.25	3.18	3.22	3.24	3.25	3.18	3.23	**3.22**
Ser	4.25	4.21	4.28	4.20	4.23	4.32	4.19	**4.24**
GlutA	17.55	17.23	17.88	17.55	17.95	18.75	17.63	**17.79**
Pro	4.41	4.34	4.56	4.43	4.55	4.66	4.39	**4.48**
Glyc	3.15	3.76	3.19	3.13	3.21	3.18	3.12	**3.25**
Ala	3.48	3.42	3.48	3.45	3.49	3.48	3.41	**3.46**
Cyst	1.30	1.30	1.29	1.28	1.19	1.12	1.29	**1.25**
Val	4.02	3.97	4.19	4.11	4.18	4.17	3.96	**4.09**
Meth	1.34	1.30	1.29	1.31	1.25	1.23	1.29	**1.29**
Isolu	3.67	3.68	3.74	3.67	3.81	3.86	3.64	**3.73**
Leu	6.76	6.75	6.81	6.68	6.85	7.00	6.57	**6.78**
Tyr	3.22	3.19	3.23	3.21	3.28	3.33	3.18	**3.23**
PhenylA	4.38	4.39	4.45	4.34	4.57	4.73	4.26	**4.45**
Trypto	1.09	1.08	1.10	1.09	1.10	1.05	1.07	**1.08**
g protein/100g sample	86.18	85.75	86.93	85.77	87.24	88.67	85.23	**86.54**
Total g N /100 g sample	13.65	13.63	13.71	13.56	13.74	13.91	13.48	**13.67**
NCF	6.31	6.29	6.34	6.33	6.35	6.37	6.32	**6.33**

NCFs were calculated as described above for Soy Protein Isolates.

Appendix Table 3: Calculation of Nitrogen Conversion Factors from Soy Flake anhydrous amino acid data

	g anhydrous AA residue/100 g sample					
AA	**2005**	**2005**	**2004**	**2005**	**2005**	**Averages**
lys	5.62	5.48	5.27	5.63	5.58	**5.52**
Hist	2.15	2.17	2.09	2.17	2.16	**2.15**
Arg	6.82	6.82	6.38	6.68	6.81	**6.70**
Asp	9.99	10.38	9.74	10.09	10.13	**10.06**
Thr	3.29	3.20	3.19	3.32	3.24	**3.25**
Ser	4.15	4.17	4.18	4.21	4.23	**4.19**
GlutA	17.55	17.72	17.75	17.79	18.08	**17.78**
Pro	4.47	4.26	4.23	4.41	4.45	**4.36**
Glyc	3.17	3.15	3.10	3.22	3.19	**3.17**
Ala	3.50	3.37	3.41	3.53	3.50	**3.46**
Cyst	1.30	1.34	1.23	1.26	1.21	**1.27**
Val	4.09	4.04	3.96	4.11	4.10	**4.06**
Meth	1.30	1.25	1.29	1.23	1.18	**1.25**
Isolu	3.67	3.68	3.64	3.66	3.70	**3.67**
Leu	6.58	6.58	6.56	6.62	6.69	**6.60**
Tyr	3.29	3.15	2.99	3.22	3.31	**3.19**
PhenylA	4.41	4.46	4.34	4.44	4.50	**4.43**
Trypto	1.11	1.07	1.13	1.19	1.10	**1.12**
g protein/100g sample	86.46	86.28	84.49	86.76	87.15	**86.23**
Total g N /100 g sample	13.72	13.67	13.32	13.74	13.8	**13.65**
NCF	6.30	6.31	6.34	6.31	6.32	**6.32**

NCFs were calculated as described above for Soy Protein Isolates.

CEFS - European Committee for Sugar Manufacturers

CEFS supports the work undertaken by the CCNFSDU on the standard on follow-up formula for older infants and young children. We think it is indeed important to guarantee that those vulnerable consumers are provided with an adequate diet which will ensure their healthy growing and development.

CEFS has always advocated for Codex work (in each committee and each working group) to rely on sound scientific evidences because we consider that it is the only way to guarantee the adoption of appropriate measures and reliable standards. We also think that only science can prevent approvals and agreements only based on political considerations which will not help the development of healthy lifestyles.

Against this background we question the reference to the WHO Guidelines: sugars intake for adults and children in the context of the standard for follow-up formula for young children (12-36 months). In these Guidelines, the WHO determines criteria for the amount of sugars as part of the whole diet. Hence, these criteria cannot be transferred to the formulation of individual foods. Besides we would like to remind that the conditional recommendation to limit sugars intake to less than 5% of total energy intake is based on data of very low quality as emphasized by the WHO itself. Moreover, being based on the review on dental caries only, this conditional recommendation is not appropriate to address concerns related to obesity. We therefore recommend some precaution to be taken on the scientific ground on which this standard is based.

ELC - Federation of European SpecialtyFood Ingredients Industries

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

Proteins

Regarding Recommendation 1

Currently, footnote 2 included in the standard refers to use of nitrogen to protein conversion factors (NCFs) for the determination of protein content based on combustion methods. In the footnote, there is reference to use of an NCF of 5.71 for soy. This language is not aligned with the Codex standard for soya proteins nor with conventional practice and formulation of infant and follow-up formulas, where the recognized NCF of 6.25 is used. Thus, we support the retention of 6.25 as the NCF used for determining soy protein content, and re-affirm that reference to use of an NCF of 5.71 for soy should be removed from Footnote 2.

As Codex observers we are fully aware of the difficulty to resolve the question of the correct NCF and therefore we would like to request the CCNFSDU to respect the recommendation of the CCMAS which was presented to the CODEX ALIMENTARIUS COMMISSION in July 2016. The recommendation was for FAO/WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors. Due to resource limitations, FAO/WHO could not take this task on as a priority, so until scientifically justified and consistent NCFs for proteins are evaluated, the existing NCF of 6.25 for soy as reported in CODEX standards for soy protein (STAN 174-1989) and vegetable protein (STAN 174-1989) should be retained.

It is regrettable that the phrase: "…value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products" was retained in the Codex standard for Infant Formulae since this is not factually correct. As noted above, an NCF value of 5.71 is not aligned with the NCF in the Codex standard for soya proteins. We request that the error in Footnote 2 in the Codex standard for Infant Formulae should not be perpetuated in Footnote 2 in the Codex standard on Follow-up Formula and re-iterate that an NCF of 5.71 for soy should be removed from Footnote 2.

Also, a decision to use a NCF of 5.71 for soy would have very significant trade and potentially serious nutritional implications. Soy protein isolate, as currently used in infant and follow-up formula products, would have to be re-categorized as a protein ingredient due to an approximate 10% reduction in the calculated amount of protein. This would likely necessitate costly formulation and/or label changes for manufacturers of follow-up formula in order to maintain current protein levels in their products. Furthermore, the use of a 5.71 conversion factor for soy could potentially lead to significant nutritional consequences, since lowering the NCF for soy to 5.71 would necessitate an increased inclusion of soy protein in formulas to maintain currently listed protein levels. This is counter to recent recommendations to reduce the protein content for follow-up formula in the CCNFSDU eWG "Review of the Standard for Follow-up Formula (CODEX STAN 156-1987), to reduce protein requirements for infants and young children by the FDA in the USA [https://www.regulations.gov/document?D=FDA-

2012-N-1210-0875] and similar recommendations published by an international expert panel of pediatric nutritionists (Suthutvoravut U et al., 2015).

Data substantiating our position is provided in the room document submitted by AOCS at the recent CODEX ALIMENTARIUS COMMMISSION meeting.

References for Recommendations 1

Suthutvoravut et al. 2015; Ann Nutr Metab 67:119-132.

Vitamin K: minimum requirements

Regarding Recommendation 2

ELC supports the minimum level for vitamin K at 4 g/100 kcal. We therefore agree with the proposal from the chairs of the eWG and support the alignment with the Codex Standard for Infant Formula which has demonstrated the history of safe use. We also believe there is a lack of evidence demonstrating the efficacy of formulas with reduced vitamin K.

Vitamin C: minimum requirements

Regarding Recommendation 3

ELC agrees with the chair recommendation to maintain the minimum vitamin C level at 10 mg/kcal as a compromise.

While we recognised that the complementary foods can provide some additional vitamin C intake, at 6 months, the quantity of complementary foods consumed is very low and the additional intake would therefore not be sufficient. It's important to protect this vulnerable population all around the globe and taking into account the key role of vitamin C is improving the absorption of iron, we believe a precautionary approach should be taken and the value of 10 mg should be retained.

Zinc: guiding upper level

Optional addition: DHA

Regarding Recommendation 5

In the CCFSNDU agenda paper, the Chairs acknowledge mixed views within the working group regarding the need for a minimum requirement for the optional addition of DHA. Based on these mixed views, the Chairs recommend acceptance of text drafted at CCNFSDU37 which established only a GUL and allows national and/or regional authorities to deviate from this suggested condition, and the condition that ARA be added at the same or higher level as DHA, and EPA must not exceed DHA.

Importantly, however, establishing a minimum level of 0.3% of total fatty acids for voluntary addition of DHA is consistent with the principles governing the addition of optional ingredients in FUF. As noted in 3.3.2.2. of the proposed revision of the FUF standard, "when any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk".

Without providing a minimum level as guidance, it will be left to national authorities to systematically evaluate the available evidence and determine an appropriate level for addition. This is a resource intensive exercise and appears unnecessary given that at least two groups (FAO and EFSA), both considered a Codex Recognized Authoritative Scientific Body (RASB), have established minimum DHA levels based on the intended effect of supporting retinal and brain development. FAO Report 91 concludes there is a convincing level of evidence that DHA plays a critical role in retinal and brain development from 0-24 months and a probable level of evidence that that an adequate intake level of 10-12 mg/kg DHA from 6-24 months is associated with these developmental benefits. EFSA has concluded that "… a cause and effect relationship has been established between the intake of infant and follow-on formula supplemented with DHA at levels around 0.3% of total fatty acids and visual function at 12 months in formula-fed infants born at term from birth up to 12 months and in breastfed infants after weaning up to 12 months" (EFSA, 2009). This conclusion confirms that benefits occur during the period of interest and are applicable to infants regardless of feeding from birth, or after weaning from breast milk, the exact scenarios for the use of FUF. EFSA recommends a DHA content between 20 and 50 mg/100 kcal.

The reported world-wide average for DHA in human milk is 0.32%±0.22 (range 0.06 to 1.4%) and for ARA is 0.47%±0.13 (range 0.24 to 1.0%). While it is true that DHA levels in human milk vary, for global health policy, it is important to meet the needs of the most vulnerable and preserve the status of the well-nourished. Setting a minimum level of 0.3% DHA in FUF at the Codex level ensures that those

infants lacking in DHA are provided meaningful levels if fed formula. It also sets an evidence-based benchmark from which higher national/regional standards for FUF can be established, as needed, based on local dietary patterns and cultural practices.

Using human milk levels as a reference is consistent with the principles laid out in 3.3.2.2. Human milk contains DHA and ARA along with an abundance of the dietary precursors of these fatty acids, alpha-linolenic acid (ALA; 18:3 n-3) and linoleic acid (LA; 18:2 n-6), respectively. However, the contribution of human milk to the complementary diet decreases dramatically during the first year of life. Intake of ALA and LA from dietary sources other than human milk is limited among older infants and young children in both developing (Michaelsen et al., 2011) and developed (Ghisolfi et al., 2013) countries. These observations are clearly delineated in section 5.5.1 of the eWG's current agenda paper. Furthermore, the Chair notes, "Almost all eWG members agreed that dietary intakes of α-linolenic acid were considered to be inadequate on a global scale (7CM; 1CMO; 3CO)." The amount of DHA and ARA produced from precursors is small, relative to the demands of growth and development (Brenna, 2016). It has been recently noted that "…none of the many studies to date has found equivalent DHA and ARA status in developing infants fed 18-carbon fatty acids compared with infants fed LCPUFAs, and this is particularly true for DHA" (Carlson and Colombo 2016). Intake of DHA by infants and young children in developing countries are also estimated to be insufficient. Thus, given the limited global intake of ALA and the limited rate of conversion of ALA to DHA, the assertion that in vivo production of sufficient DHA to support developmental needs, is not substantiated.

Finally, it is worth clarifying whether a minimum level for DHA would be consistent with legal precedents. The Chairs have noted that "…minimum values for optional ingredients have not been established for any other optional ingredients listed in either the Codex Infant Formula Standard, or the proposed draft Standard for Follow-up Formula (REP16/NFSDU Appendix III)". While this statement accurately describes these two standards, minimum values for optional ingredients for this age group is not unprecedented. The Codex Guidance on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991) provides for optional addition of vitamins and minerals and notes the following: "6.6.1.3 If the dietary intake data for the target population is not available, the vitamins and minerals listed in the Table in the Annex to these Guidelines can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food."

References for Recommendation 5

Food and Agricultural Organization of the United Nations (FAO), 2010. FAO Food and Nutrition Paper 91.

Forsyth et al., 2016. Ann Nutr Metab 69(1):64-74

Ghisolfi J,et al., 2013. Public Health Nutr 16(3), 524–534.

Michaelsen KF, Dewey KG, Perez-Expositio AB, et al. 2011. Maternal Child Nutr 7 (Suppl. 2):124–140.

Optional addition: L(+) lactic acid producing cultures

Regarding Recommendation 6

ELC supports the permission for the optional addition of cultures for the 2 purposes of acidification on one side and nutritional purpose on the other side. However, we believe the focus for the nutritional use should not be on L(+) or D(-) lactic acid producing cultures but should be based on safety requirements taking into account:

- Whole Genome Sequence mining for evidence of virulence factor and toxin production
- Antimicrobial resistance profile should be determined with no potential to transfer (according to EFSA FEEDAP, 2012)

Demonstration of safety and suitability for nutritional purpose:

The aspect of safety for all "non-pathogenic lactic acid- producing cultures" should be clearly demonstrated, including whole genome sequence mining, where it is clear there is no risk of virulence factor production or toxin production (Pariza et. al); antibiotic resistance should be established with no potential of antibiotic resistant gene transfer (as outlined by EFSA FEEDAP)

The safety of L. fermentum strain CECT5716 was referenced in regard to use in infant formula and also in follow-on formula, demonstrating safety of this strain for use in infants. (López-Huertas, 2015) Safety was initially determined using a randomized, placebo controlled clinical trial of 188 breast-fed, six-month old infants, providing a dose of 2x108 CFU/day of L. fermentum CECT5716 in infant formula. No adverse events were reported, and no difference in growth rate was seen at any point during the six-month trial, further indicating safety. This study clearly demonstrated efficacy, documenting a 46%

reduction in gastrointestinal illness in the experimental group compared to placebo, and a 26% reduction in the rate of respiratory infections. The second randomized, placebo-controlled study described by Lopez-Huertas involved 137 breast-fed, one month old infants. The experimental group was administered 10^7 CFU/g in infant formula. This study took place through six months of age. The adverse events of reflux and infantile colic was the same between experimental and control groups, and the growth rates were the same. No adverse events associated with probiotic ingestion were detected, and the probiotic supplement was well-tolerated. In-line with the previously document study, the efficacy of the probiotic was clearly demonstrated in the experimental group, with a 71% reduction in gastrointestinal illness in the experimental group ingesting L. fermentum CECT5716.

The U.S. FDA has received GRAS notifications for L. reuteri strains, where scientific evidence has been presented to establish the safety of these probiotic strains. (FDA) FDA has no questions on this notification, GRN#440, indicating they do not object to the safety submission. L. reuteri DSM17938 has also been submitted for use as a food ingredient, specifically for use in powdered whey-based term infant formula at a minimum level of 106 colony forming units per gram (cfu/g), but not higher than 108 cfu/g of powdered formula, produced in accordance with current good manufacturing practices.

References for the recommendation 6:

Pariza MW, Gillies KO, Kraak-Ripple SF, Leyer G, Smith AB. Determining the safety of microbial cultures for consumption by humans and animals. Regul Toxicol Pharmacol. 2015 Oct;73(1):164-71.

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). (2012). Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance. EFSA Journal, 10(6), 2740.

FDA, U. (n.d.). U.S. Food and Drug Administration GRAS Notices. Retrieved July 30, 2015, from U.S. Department of Health and Human Services: http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&sort=GRN_No&order=DESC&startrow=1&type=basic&search=reuteri

López-Huertas, E. (2015). Safety and Efficacy of human breast milk Lactobacillus fermentum CECT 5716. A mini-review of studies with infant formulae. Beneficial Microbes, 6(2), 219-224.

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

Regarding Recommendation 8

Mandatory (core) composition:

We agree that the mandatory (core) composition can be limited to key nutrients if other nutrients, ingredients or substances can be added.

Optional Additions:

The Chairs propose two options for the addition of optional ingredients for follow-up formula for young children. Option 1 uses the essential composition of follow-up formula for older infants and option 2 foresees a principles-based approach.

Should Option 1 being the retained option, we believe there is a need for modification. Option 1, which uses the essential composition of formula for older infants as a reference point, provides much more defined guidance for the development of nutritionally adequate formula for young children. However, limiting to only the essential ingredients ignores the extensive deliberations and evaluations associated with decisions to allow certain optional ingredients, at particular levels, in formula for older infants. It is respectfully requested, therefore, that both the essential and optional ingredients decided upon for older infants be recognized for formula for young children. This is particularly relevant for DHA where a global deficit has been identified (Forsyth et al., 2016) and the dietary precursor to DHA, ALA, has been recognized as limited in the diets of young children world-wide and conversion from ALA to DHA insufficient to meet DHA needs (Pawlosky et al., 2006; Carnielli et al., 2007).

We have a preference for option 2 as it opens the possibility to add nutrients, substances or ingredients which are safe and suitable. In particular as indicated above in our comments on option 1, we believe the option to add DHA should be given to operators in order to propose adequate formula for young children.

References for Recommendations 8 and 12

Carnielli VP, Simonato M, Verlato G, et al. 2007. Am J Clin Nutr 86:1323-30.

Forsyth et al., 2016. Ann Nutr Metab 69(1):64-74

Pawlosky RJ, Lin YH, Llanos A, et al. 2006. Pediatr Res 60: 327–333.

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

Regarding Recommendation 12

The Chairs recommend a minimum level of ALA for addition in formula intended for young children. This is an important recommendation, but does not go far enough. The Chairs note in their discussion that, "Dietary intake data from low income countries have indicated that mean intakes of α-linolenic acid and DHA were low…". Given that a deficit of DHA is already recognized in low income countries, and it is known that conversion is poor from ALA to DHA (Pawlosky et al., 2006; Carnielli et al., 2007), why then would the composition of formula for young children not benefit from allowance for optional addition of DHA, as described for older infants? In fact, two recent evidence-based reviews (Brenna, 2016; Carlson and Colombo, 2015) and results from one new study (Hatanaka et al., 2016) confirm the inadequacy of ALA to meet needs of DHA in early life. Therefore, we respectively request that optional addition of DHA, as described in recommendations for older infants, be included here.

References for Recommendations 8 and 12

Brenna TJ. 2016. Nutr Rev 74:329-336.

Carlson, S.E. and Colombo, J. 2016. Advances in Pediatrics 63:458-471.

Carnielli VP, Simonato M, Verlato G, et al. 2007. Am J Clin Nutr 86:1323-30.

Hatanaka et al., 2016. Prostaglandins, Leukotrienes and Essential Fatty Acids 108(2016)51–57.

Pawlosky RJ, Lin YH, Llanos A, et al. 2006. Pediatr Res 60: 327–333.

Regarding Recommendation 14

Whereas we basically can agree with the proposed text on types of carbohydrates we do not support the (additional) proposal on the establishment of a minimum lactose content of 50% of total carbohydrates, as being too prescriptive. There is no rationale for a preference to lactose, only, whereas there are other fully digestible carbohydrates such as maltodextrins and starches that have the advantage of producing lower osmolality, or carbohydrates with similar beneficial properties compared to lactose, such as e.g. isomaltulose, being slowly digestible on the one hand, but providing full energy in a low glycaemic way, whilst being fully digestible, on the other.

We would like to also point out those carbohydrates such as sacharose and gluten free starches may be used as carriers in nutrient preparations in order to obtain optimal homogeneity of the ingredients or because of food technological reasons. The final product would contain these carriers only to a very little amount.

We therefore propose to amend the text of the recommendation and to delete the text under "Additional options for further discussion" in recommendation #14 as follows:

Recommendation 14*:*

…

[Lactose should be the preferred carbohydrates in [name of the product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Carbohydrates such as sucrose and/or fructose and/or gluten free starches should not be added, unless needed as a carbohydrate source or as carriers in nutrient preparations. Sugars, other than lactose, should not exceed 10% of available carbohydrate].

~~*Additional options for further discussion:*~~

~~*Lactose should be the preferred carbohydrates in formula based on milk protein [and should provide not less than 50% of total carbohydrates].*~~

Regarding Recommendation 15

ELC agrees with the minimum and GUL level proposed by the chairs for vitamin C as well as the minimum and maximum levels proposed for iron.

Regarding Recommendation 16

ELC agrees with the minimum and GUL levels proposed for riboflavin and vitamin B12. For calcium, we believe the minimum level should be increased due to increased requirements.

Regarding Recommendation 17

Vitamin A is key in many countries where the risk of deficiency is high and the consequences are such deficiency as major public health issue. We understand the EFSA position regarding the risk of excessive vitamin A intake but believe vitamin A should be on the list of mandatory nutrients with a maximum limit in order to avoid the risk of excessive intake. Therefore we favour the alternative proposal which is in line with the recommendation from the international group of experts (Suthutvoravut et al. in 2015).

References for Recommendations 17

Suthutvoravut et al. Ann Nutr Metab 67:119-132.

Regarding Recommendation 18

Vitamin D is a key vitamin with multiple roles including in building bones and immunity. Vitamin D is found in animal derived products which are not necessarily consumed in high quantity by this age group. On a global scale, vitamin D status is insufficient in this population including in sunny countries. In addition, it's not generally accepted that the requirements are actually higher than previously assumed. This means that the gap in intakes has become even bigger.

Therefore we believe vitamin D is fitting the criteria to be included as mandatory nutrients. We understand the fear of adverse effects so we agree with setting a maximum level instead of a GUL.

ENSA - European Natural Soy and Plant-based Food Manufacturers Association

Recommendation 1

ENSA supports the retention of a nitrogen conversion factor of 6.25 used for determination of protein content but this should also be the case for soy protein. In the footnote 2 however there is reference to use 5.71 for soy protein.

This language is not aligned with the Codex standard for soya proteins nor with conventional practice and formulation of infant and follow-up formulas, where the recognized NCF of 6.25 is used. Thus, we support the retention of 6.25 as the NCF used for determining soy protein content, and re-affirm that reference to use of an NCF of 5.71 for soy should be removed from footnote 2.

For a more detailed explanation, please see attached a joint ENSA-EUVEPRO statement on the protein conversion factor.

Recommendation 7

ENSA agrees to divide the standard for follow-up formula in 2 separate parts; Section A FUF older infants, Section B for product for young children.

Recommendation 8

Regarding optional additions, ENSA agrees with option 2 only since this is in line with the approach of diversified diet in young children. Young children clearly differ from infants.

Concerning footnote 2 regarding protein requirements for older infants and the nitrogen conversion factor, ENSA supports the retention of 6.25 as the NCF for all protein including soy protein. The reference to use an NCF of 5.71 for soy should be removed from footnote 2 since it is not aligned with the Codex standard for soya proteins nor with conventional practice and formulation of infant and follow-up formulas, where the recognized NCF of 6.25 is used. Thus, we support the retention of 6.25 as the NCF used for determining soy protein content, and re-affirm that reference to the use of an NCF of 5.71 for soy should be removed from Footnote 2.

For a more detailed explanation please see attached a joint ENSA-EUVEPRO statement on the protein conversion factor.

Recommendation 10

ENSA agrees with setting a maximum level for total carbohydrates.

Recommendation 11

ENSA questions the use of casein as a reference since milk clearly contains other proteins as well. As mentioned in the report the PDCAAS has been in use for more than 20 years and continues to be endorsed.

Recommendation 14

Comment:

For plant-based products for young children based on soy, lactose cannot be considered as the preferred carbohydrate or sugar; adding lactose is not acceptable because the plant-based products are free from dairy and animal derived ingredients. For consumers this is highly important.

The mandatory use of animal derived components (including lactose) in plant-based products is not acceptable. Other types of sugars are needed for palatability such as sucrose and fructose….

Whilst accepting the importance of limiting the amount of sugars in the diet of young children, ENSA requests the deletion of the maximum amount of sugars other than lactose at 10% of the carbohydrates for young children formula for plant-based products; otherwise it would imply that a product which is able to carry the 'low in sugars' nutrition claim in line with EU nutrition & health claims regulation (i.e. less than 2,5 g of sugars/100 ml) is not acceptable for use in young children, while 2,5 g /100 ml i.e. 3,9 g/100 kcal (for a product containing 64kcal/100 ml) is 51% lower than the sugar content of full fat cow's milk (7,6 g/100 kcal) and 62% lower than that of semi-skimmed milk (10,2 g/100 kcal).

There is no scientific evidence that sugars other than lactose are harmful when consumed in low amounts.

Therefore ENSA requests to align the maximum level of sugars (other than lactose) in plant-based products to the level of lactose in milk i.e. for full fat cow's milk 7,6 g/100 kcal and for semi-skimmed milk 10,2 g/100 kcal (approximately 4.7 g/100 ml).

Labelling

Recommendation 20

Comment:

ENSA agrees to differentiate between follow-up formula for older infants and products for young children, but the definition needs to be adapted to include plant-based products based on soy.

Recommendation 21

Comment:

The definition needs to be adapted to include plant-based products based on soy since these are not based on milk from cows or other animals but rather based on soy/soy protein; also these products cannot use the denomination of 'milk', and thus are restricted from using the terms 'fortified milk for young children' and 'processed milk for young children'; therefore another name is proposed such as 'drink for young children'

ENSA/EUVEPRO - European Natural Soy and Plant-based Food Manufacturers Association/ European Vegetable Protein Association

Footnote on Protein Conversion Factors

Currently, there is a footnote included in the standard that refers to the use of nitrogen to protein conversion factors (NCFs) for the determination of protein content based on combustion methods. In the footnote, there is reference to the use of an NCF of 5.71 for soy. This language is not aligned with the Codex standard for soy proteins nor with conventional practice and formulation of infant and follow-up formulas, where the recognized NCF of 6.25 is used. Thus, we support the retention of 6.25 as the NCF used for determining soy protein content, and re-affirm that reference to the use of an NCF of 5.71 for soy should be removed from Footnote 2.

We request the CCNFSDU to respect the recommendation of the CCMAS37 which was presented to the CODEX ALIMENTARIUS COMMISSION in July 2016. The recommendation was for FAO/WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors. Due to resource limitations, FAO/WHO could not take this task on as a priority, so until scientifically justified and consistent NCFs for proteins are evaluated, the existing NCF of 6.25 for soy as reported in CODEX standards for soy protein (STAN 175-1989) and vegetable protein (STAN 174-1989) should be retained. We reiterate that the NCF of 6.25 for soy proteins is also the recognised factor in many national jurisdictions, including the European Union legislation on food labelling and the EU regulation on infant and follow-on formula, which was based on the "Scientific Opinion on the essential composition of infant and follow-on formulae" by EFSA, the European Food Safety Agency, reconfirming the NCF of 6.25 in their in review in 2014 [EFSA Journal 2014;12(7):3760].

It is regrettable that the phrase: "…value of **5.71** as a specific factor for conversion of nitrogen to protein in other soy products" was retained in the Codex standard for Infant Formulae since it:

- adds confusion;

- contradicts the NCF of 6.25 employed in the body of the standards;
- is not substantiated scientifically.

Furthermore, as noted above, an NCF value of 5.71 is not aligned with the NCF in the Codex standard for soy proteins. We request that the unfortunate reference to 5.71 in Footnote 2 in the Codex standard for Infant Formulae should not be perpetuated in Footnote 2 in the Codex standard on Follow-up Formula, and re-iterate that the NCF of 5.71 for soy should be removed from Footnote 2.

Also, if the NCF of 5.71 were to be used for soy, this would have very significant trade and potentially serious nutritional implications. Soy protein isolate, as currently used in infant and follow-up formula products, would have to be re-categorized as a protein ingredient due to an approximate 10% reduction in the calculated amount of protein. This would likely necessitate costly formulation and/or label changes for manufacturers of follow-up formula in order to maintain current protein levels in their products. Furthermore, the use of the 5.71 conversion factor for soy could potentially lead to significant nutritional consequences, since lowering the NCF for soy to 5.71 would necessitate an increased inclusion of soy protein in formulas to maintain currently listed protein levels. This is counter to recent recommendations to reduce the protein content for follow-up formula in the CCNFSDU eWG "Review of the Standard for Follow-up Formula (CODEX STAN 156-1987), to reduce protein requirements for infants and young children by the FDA in the USA [https://www.regulations.gov/document?D=FDA-2012-N-1210-0875] and similar recommendations published by an international expert panel of pediatric nutritionists (Suthutvoravut U 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, Ann Nutr Metab 67: 119-132).

We fully endorse the AOCS submission to CCNFSDU38 which provides more detailed scientific evidence, and substantiates the position in this document.

HKI - Helen Keller International

GENERAL COMMENTS

1. PRODUCT VERSUS FOOD

Throughout the document the word 'food' must (where relevant) be replaced with the word 'product' to be in line and consistent with the decision made at the last meeting that follow-up formula will be referred to as a product not food in the definitions section 2.1.1. Thus as examples, the title of 9.1 must read 'The Name of the Product' and 9.1.1 must read 'The name of the product shall be…'

SPECIFIC COMMENTS

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

4.2 Principles for determining mandatory requirements

One of the three principles currently suggested to help guide and justify nutrient additions is "contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale". However no definition of "global scale" is given. The numbers of children 1-3 years of age affected by inadequate intakes of nutrients is higher in low and middle income countries than those in high income countries. Yet the "global scale" issue has been used to not include nutrients in the core list.

The Sept. 2016 paper states since "vitamin A deficiency is relatively rare in European countries, the USA and Canada, the Chairs are of the view that the evidence does not support Principle 1, that the consumption of vitamin A is inadequate on a global scale". However, Europe and North America represent only 15% of the world's population (http://www.worldometers.info/world-population/) and an even lower percentage of young children. Why less than 15% of the world represent a "global scale"?

Additionally, "It is the proposal of the Chairs' that vitamin D is not included as this point in time as a mandatory (core) nutrient for addition to follow-up formula for young children. Further consideration of whether the evidence supports the addition of vitamin D based on the 'contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale' (Principle 1) is required."

Also the Secretariat stated that "Data on zinc intakes and zinc deficiency are limited and sometimes inconsistent. Further consideration of whether the evidence supports the addition of zinc based on its 'contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale' (Principle 1) is required."

We believe that this principle "...on a global scale" is not appropriate to guide development of this standard. Thus nutrients may need to be added to products for young children to prevent deficiencies in many countries even if not considered a priority in high income countries, and therefore "not on a global scale" as currently proposed.

SECTION B: (NAME OF PRODUCT) FOR YOUNG CHILDREN

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.3 (NAME OF PRODUCT) FOR YOUNG CHILDREN PREPARED READY FOR CONSUMPTION SHALL CONTAIN PER 100 KCAL (100 KJ) THE FOLLOWING NUTRIENTS WITH THE FOLLOWING MINIMUM AND MAXIMUM OR GUIDANCE UPPER LEVELS (GUL), AS APPROPRIATE.

b) Lipids

We agree with the current proposal and support a minimum fat level at 4.4 g/100 kcal to match that proposed for older infants. We also support the minimum level of α-linolenic acid of 50 mg/100 kcal.

Rationale:

There is no evidence that most children have higher intakes of fat from 12-36 mo of age compared to infants, but in low and middle income countries they often have less if they are no longer breastfed (Huffman et al, 2011).

A minimum fat level of at least 4.4 g/100 kcal should be specified to ensure that the product contains sufficient fat needed by young children for growth, development and health status. If fat is too low in the product there can be also be deficiencies in amount/absorption of fat soluble vitamins and limited intake of essential fatty acids. Semi-skimmed cows' milk (3.5 g/100 kcal) (Appendix 1, Table 1 of Sept. 30, 2016 report) is not suitable for young children aged 12-24 months since it could compromise intakes of dietary fat. Breastmilk contains on average 6.1 g and cow's milk 5.5 g/100 kcal (Appendix 1, Table 1 of Sept. 30, 2016 report). Matching that in the FUF standard for older infants is appropriate.

c) Carbohydrates

In addition to a maximum on available carbohydrates, there should be a limitation on free sugars.

We recommend that the footnote of the c) carbohydrates section be revised to include a maximum for percent of total energy:

c) Carbohydrates [Available carbohydrates)

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	-	[12.0]	-
g/100 kJ	-	[2.9]	-

[4) Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source. Sugars, other than lactose, should not exceed 10% of available carbohydrate **and 5% of total energy**].

Rationale:

As stated in the report (p. 28) "consumption of 300 mL to 500 mL of follow-up formula for young children would provide 20-33% of energy requirements in the diet of young children. Products [*in daily amounts consumed]* would need to contain less than 8 g of added sugars to provide appropriate levels of added sugar in proportion to the contribution of energy these products have to the diet." Using 300 ml (195 kcal) consumed per day, 8 gm of sugar would equal 2.7 gm of sugar (10.8 kcal) per 100 ml (for a total of 32.4 kcal per day, equaling 3.4% of total energy. With 500 ml per day, and 2.7 gm/100 ml, daily free sugar intake from the product would equal 5.7% of total energy. WHO (2015) recommended an intake of free sugars of less than 10% of energy and conditionally recommended a further reduction to less than 5%. The International Expert Group (IEG, Suthutvoravut et al, 2015) also recommended less than 5% of energy content for FUF. To ensure 500 ml of product contains less than 5% of energy, a lower amount of free sugars per day from consumption of the product than 8 gm would be preferable. Specifying this by clearly stating <5% of energy in the footnote is a way to clarify the issue, since this ensures others will understand the intent of the guidance, since most do not think in terms of "percent of carbohydrates" in a product.

The addition of free sugars makes the product sweeter than breastmilk which has no free sugars. It is very important to ensure that the product does not taste excessively sweet as this could lead to children developing a preference for sweetened products in early childhood and have an "impact on flavour development affecting taste preferences" (European Commission, 2016).

3.1.3. Additional Options for Consideration

Vitamins A, D and zinc should be included in the Standard as core nutrients. We recommend that the section on "additional options for consideration" be revised so that these nutrients are part of the core:

Rationale:

~~***(ADDITIONAL OPTIONS FOR CONSIDERATION)***~~

[ZINC]

[UNIT	**MINIMUM**	**MAXIMUM**	**GUL]**
[MG /100 KCAL	[0.5]	-	[1.8]
[MG /100 KJ	[0.12]	-	[0.43]

[VITAMIN A]

UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
MG RE8) /100 KCAL	[60]	[180]	**-**
MG RE8) /100 KJ	[14]	[43]	**-**

[8) expressed as retinol equivalents (re)

1 µg re = 3.33 iu vitamin a = 1 µg all-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.]

[VITAMIN D]

[UNIT	**MINIMUM**	**MAXIMUM**	**GUL]**
[MG9) /100 KCAL	[1.5]	[4.5]	**-**
[MG9) /100 KJ	[0.36]	[1.08]	**-**

[9) Calciferol. 1 µg calciferol = 40 iu vitamin d.]

Vitamin A, D, and zinc are problem nutrients among young children in many parts of the world with major health problems when there is inadequate intake (and/or lack of sun exposure for vitamin D). Another concern is if infants less than 6 mo of age consume these products instead of breastmilk or infant formula (which is required to contain vitamins A and D and zinc), major deficiencies can occur leading to blindness, rickets, and health consequences of inadequate zinc intake, including increased risk of diarrhea and pneumonia, the two largest causes of death among children under age five years. These two illnesses are even more devastating among non-breastfed infants.

In many low income countries, local standards require the inclusion of these nutrients to such products, and thus ensuring their addition to the Standard will help promote trade.

1. NAME OF THE PROPOSED REVISED DRAFT STANDARD FOR FOLLOW-UP FORMULA CODEX STAN 156-1987 AND PREAMBLE

We recommend that the name of the standard be revised to read:

STANDARD FOR FOLLOW-UP FORMULA [FOR OLDER INFANTS] AND [~~(NAME OF PRODUCT)~~ **FORTIFIED MILK** FOR YOUNG CHILDREN]

Rationale:

We believe that the name of the Standard 'Standard for Follow-up Formula (CODEX STAN 156-1987)' must be reviewed.

Using only the term 'Follow-up Formula' implies that both products covered by the standard could both be used for infants. Research has shown that mothers have interpreted 'Follow-up Formula' in this manner in the United Kingdom, where 16% of mothers in a 2010 national infant feeding survey reported that they first used follow-up formula before 6 months of age. Of mothers who had never worked, 26%

reported that they had given their baby follow-on formula before 6 months of age (McAndrew et al., 2010). One-third (32%) of mothers reported they did not know the difference between various breast-milk substitute products, and health workers were unable to differentiate them as well (Crawley and Westland, 2016). In Senegal, nearly 10% of mothers of infants and children under age two were unable to state what stage of formula they gave their infants (ARCH research, 2016, unpublished analyses). Other research by Cattaneo et al. (2014) has also shown the confusion that exists between these different products amongst mothers, especially considering the way manufacturers label these products, clearly indicating the need for Codex to address this critical issue for the reason of consumer protection.

Cattaneo et al. found that only 43% of mothers in a study in Italy were able to assign the correct meaning, in terms of age of use, after careful reading of a follow-up formula advertisement.

As reported by Watson and Heath (2013), "recommendations for the minimum age of follow-up formula introduction are not always followed. France, Ireland, Luxembourg, and the United Kingdom all reported introduction earlier than their country's recommendation, as did the developing countries Ghana and the Philippines. There is a large range in the age at which follow-up formula was first introduced to the child. The earliest follow-up formula introduction reported was at one month by 2% of children in a United Kingdom study of 9,416 mothers (8). Even within countries there was a range of ages at which follow-up formula was introduced, such as in Sweden, where 44% of children were introduced to follow-up formula at less than four months old (11), 30.5% at four to six months, and 50% at six months or older… Rates of follow-up formula consumption at or before six months of age were reported by eight developed countries and three developing countries."

It is important to note that the follow-up formula for young children (12-36 months) includes fewer proposed nutrients (13) than follow-up formula for older infants or the 32 suggested in the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991).

Follow-up formula for young children (12-36 months) covered in this standard could potentially be fed to older infants (6 to 12 months) with no negative nutritional consequences if prepared hygienically, and given in addition to adequate complementary foods. However, if follow-up formula for young children is the only breastmilk substitute fed to an infant <6 months of age or to older infants not receiving adequate complementary feeding, nutritional deficiencies would most definitely result since the proposed composition only requires 13 nutrients, while the Infant Formula Standard and the proposed follow-up formula for older infants standard both require 32 nutrients. For example, thiamin deficiency due to consumption of inadequate soy infant formula was found in in Israel (Mimouni-Bloch A, 2005). Young infants <6 months of age consuming the proposed follow-up formula for young children (12-36 months) and older infants not receiving adequate complementary feeding would be similarly at risk, since thiamin is not required, nor are numerous other nutrients in the composition currently under discussion (including niacin, vitamin B6, vitamin E, vitamin K, niacin, folic acid, etc.) If the 2 products being considered under this standard have clearly different names, this confusion and misuse is less likely to occur.

It is important to also consider that since the follow-up formula for young children standard under consideration requires the addition of fewer nutrients, it is likely to be less costly to manufacture and therefore could be sold at a lower cost than infant formula or follow-up formula for older infants. Given that consumers sometimes struggle to distinguish between different types of breastmilk substitutes, families may choose these lower cost products assuming that they are comparable in composition to more expensive infant formulas.

2. PREAMBLE

We recommend that the preamble be revised to include the form and a generic role for the products and that it thus reads:

[PREAMBLE

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with [Fortified milk ~~(Name of Product)~~ for Young Children~~.~~] **in liquid or powdered form intended for use as a substitute for human milk and/or other milks.**]

Rationale:

The Committee agreed that this standard and the infant formula standard should be as aligned as possible and this proposed additional wording is adapted from the infant formula standard.

In addition we believe that there should be as much generic clarity as possible provided in the preamble.

We therefore strongly believe that the preamble should include the role of the products included in the standard. The role of both the products included in the standard is to replace the milk that the older

infant/young child is consuming. As the global recommendation is that a child should continue to receive breastmilk to '2 years and beyond', breastmilk should serve as the 'milk' component of these older infants/young children's diets. These products thus *de facto* function as breast-milk substitutes because their consumption displaces rather than complements the intake of breastmilk. The WHO Scientific and Technical Advisory Group (STAG) that looked at this issue concluded that there is sufficient evidence that this displacement occurs. Despite compositional differences, infant formula, follow-up formula for older infants, and fortified milk for young children all partially or totally replace the consumption of breastmilk and therefore should be considered to be breast-milk substitutes.

In cases where the older infant (6 – 12 months) cannot be fed human milk, the global recommendation is to use infant formula. In cases where the young child (12 – 36 months) cannot be fed human milk, the global recommendation is cow's milk. Neither of these recommendations invalidate the fact these products *de facto* displace the intake of breastmilk. The products under this standard will still *de facto* displace breastmilk if, as is suggested by some members of the working group, they are "*to be used as a supplement to the diet to support adequacy of intakes of nutrients of key global concern for this age group, or as the liquid fraction of the diversified complementary diet when energy and nutrient intakes may not be adequate to meet the nutritional requirements of young children*." It must thus be clear in the preamble that the role of these products regardless is to replace breastmilk and/or cow's milk and / or other milks.

The Secretariat wrote "It is recognised that in general follow-up formula for young children is often used as a substitute, alternative or replacement for cows' milk, and could supplement the diet to provide those nutrients which are of key global concern for this age group."(CCNFSDU, 2016, p19).

To support this claim, they quote from a European Commission (2016) report that states: "…breastfeeding decreases significantly after the age of one year in the different Member States, both in terms of rates and intakes. Formula products are competing with cows' milk in the diet of young children, and differences in the preference exist depending on the Member State. However, it can generally be reported that consumption of young-child formula is at its highest in the age range 12-18 months."

Breastfeeding rates among 28 member states in the EU (out of 129 countries with data worldwide) are not representative of the breastfeeding rates in the world. While women in the EU may be more likely to substitute a product for young children for cows' milk, in most other parts of the world, a high proportion of women are still breastfeeding their 1 to 2 year old children (See Table 1). For the world as a whole, ¾ of children 12-15 mo of age and half of those 20-23 mo of age are still breastfed. In the least developed countries, these figures are 91% and 63% respectively. Clearly for the majority of children in the world, a product for young children would replace breastmilk, not cows' milk.

Since Codex is mandated to develop 'international food standards, guidelines and codes of practice', using data from only the EU to support the view that products are replacements for cows' milk and not breastmilk is inappropriate. The WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children adopted as part of WHA Resolution 69.9 at the World Health Assembly in May 2016 is clear—products for children 1-3 years of age are breastmilk substitutes.

Table 1. Percent of young children breastfeeding at ages 1 and 2 years by region

Countries and areas	**Breastfeeding at 1 year (12–15 months, %) 2010-2015***	**Breastfeeding at age 2 (20–23 months, %) 2010-2015***
Africa	86	49
Sub-Saharan Africa	89	52
Eastern and Southern Africa	90	60
West and Central Africa	87	46
Middle East and North Africa	71	33
Asia**	71	52
South Asia***	87	75
East Asia and the Pacific****	51	24
Latin America and the Caribbean	51	26

Central and Eastern Europe and the Commonwealth of Independent States (CEE/CIS)*****	56	29
Least developed countries	91	63
World**	74	49
Notes:		
	* Data refer to the most recent year available during the period specified in the column heading (2010-2015) ** Aggregate uses older data for China and India (2008 data from China and 2005-2006 and 2007-2008 data from India) *** Aggregate uses older data for India (2005-2006 and 2007-2008 data from India) **** Aggregate uses older data for China (2008 data from China) *****Aggregate excludes Russian Federation for which no data exists	

SCOPE

We recommend that the 1. Scope be revised to read:

[1. SCOPE

1.1 Section A of this Standard applies to ~~the compositional, safety and labelling requirement of follow-up formula for older infants~~ **follow-up formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in helping to meet the normal nutritional requirements of older infants.**

1.1.1 Section A of this standard contains compositional, quality, safety and labelling requirements of follow-up formula for older infants.

1.1.2 Only products that comply with the criteria laid down in this section of this Standard would be acceptable for being named as follow-up formula for older infants.

1.1.**3**~~1~~ The application of Section A of this Standard should take in to account the recommendations made in **the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, the WHO Guidance on Ending the Inappropriate Promotion of Food for Infants and Young Children and relevant World Health Assembly resolutions 32.22, 39.28, 47.5, 49.15, 54.2, 55.25, 58.32, 59.21, 61.2, 63.23, 69.9.**

1.2 Section B of this Standard applies to ~~the compositional,~~ **quality**, ~~safety and labelling of [(name of product)~~ **[fortified milk for young children] in liquid or powdered form intended for use as a substitute for human milk in helping to meet the normal nutritional requirements of young children as part of the progressively diversified diet when nutrient intakes may not be adequate.**

1.2.1 Section B of this standard contains compositional, quality, safety and labelling requirements of [fortified milk for young children].

1.2.2 Only products that comply with the criteria laid down in this section of this Standard would be acceptable for being named as fortified milk for young children.

1.2.**3**~~1~~ The application of Section B of this Standard should take in to account the recommendations made in the **International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, the WHO Guidance on Ending the Inappropriate Promotion of Food for Infants and Young Children and relevant World Health Assembly resolutions 32.22, 39.28, 47.5, 49.15, 54.2, 55.25, 58.32, 59.21, 61.2, 63.23, 69.9.**

As there is a difference in approach between the 2 other relevant Codex standards that we believe this text should be based on, namely the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and the Guidelines on Formulated Complementary Foods for Older Infants and Young Children, we are willing for 1.1 and 1.2 to refer to the definition text rather than repeat the full definition text. This would be in alignment with the Guidelines on Formulated Complementary Foods for Older Infants and Young Children.

These sections would thus read:

1.1	Section A of this Standard applies to ~~the compositional, safety and labelling requirement of follow-up formula for older infants~~ **follow-up formula, as defined in Section 2.1 below, in liquid or powdered form.**
1.2	Section B of this Standard applies to ~~the compositional, **quality**, safety and labelling of [(name of product)~~ **[fortified milk for young children], as defined in Section 2.1 below, in liquid or powdered form.**

In addition, we are willing to accept that the actual WHA references appear as a footnote. Thus the text we proposed for 1.1.3 and 1.2.3 (above) would then read:

1.1.**3**~~1~~	The application of Section A of this Standard should take in to account the recommendations made in **the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, the WHO Guidance on Ending the Inappropriate Promotion of Food for Infants and Young Children and relevant World Health Assembly resolutions[1].**
1.2.**3**~~1~~	The application of Section B of this Standard should take in to account the recommendations made in the **International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, the WHO Guidance on Ending the Inappropriate Promotion of Food for Infants and Young Children and relevant World Health Assembly resolutions[1].**
Footnote 1: WHA Resolutions 32.22, 39.28, 47.5, 49.15, 54.2, 55.25, 58.32, 59.21, 61.2, 63.23, 69.9.	

Rationale:

Alignment

We have altered the text to be in alignment, as has been agreed by the Committee, with the Infant Formula and Formulas for Special Medical Purposes Intended for Infants standard as far as is possible. We have thus:

- Altered 1.1 and 2.1 to be aligned and to include the form and role of the products.
- Made 1.1.1 (now 1.1.3) and 1.2.1 (now 1.2.3) a separate point in alignment with the Infant Formula and Formulas for Special Medical Purposes Intended for Infants standard and added the word ‘quality’ to also ensure alignment. We believe the issue of quality is critically important as this standard is addressing a product fed to one of the most vulnerable groups, older infants and young children.

  The proposed wording is taken directly from the Infant Formula and Formulas for Special Medical Purposes Intended for Infants standard.
- Added text as 1.1.2 and 1.2.2, and this proposed additional wording is adapted from the text in the Infant Formula and Formulas for Special Medical Purposes Intended for Infants standard. We believe it is critically important that this vulnerable group be protected from possible harm caused by products using the names provided in this standard but not meeting the requirements set out in the standard.
- Added text as 1.1.3 and 1.2.3 using text adapted from the Infant Formula and Formulas for Special Medical Purposes Intended for Infants standard. See additional rationale that follows:

Coherence

We believe that specific reference must be made in to the International Code of Marketing of Breast-milk Substitutes and relevant WHA resolutions, as both are eminently relevant.

This is firstly to ensure, as the Committee has agreed, alignment with other relevant Codex texts, namely the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72 – 1981) and the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991).

Secondly, it is critical to make specific mention of relevant policies and WHA resolutions so as to ensure that there is coherence between the work of Codex and WHO/FAO policies, strategies and guidelines. We note the discussion on this issue at the 38th Codex Alimentarius Commission and believe that this is a Codex document where coherence is critical and referencing relevant WHA guidelines and WHA resolutions underscores the way in which Codex is supporting the priority areas identified by Member States. We also draw attention to the fact that the precedent has been set in other Codex standards to make reference to WHA resolutions and strongly disagree with the comment made that "*it is not appropriate that [Codex] product standards deviate in their scope into areas of public health policy or statements on nutritional policy. Policy statements relating to health are beyond the scope of the Codex Alimentarius*" or the query as to the *"legitimate basis to include those statements based on the Codex Rules of Procedure."* At a time when infant and young child feeding and health is under the global spotlight and countries are striving to meet the Sustainable Development Goals, coherence and cross-referencing between Codex and WHO/FAO decisions and policies must become a reality.

Labels as a promotional tool

We note with concern the view of some members of the electronic working group regarding the relevance of including and referencing WHA resolutions within the Standard, specifically the view that labelling is "considered a separate entity" from marketing practices.

It is our strong opinion that the evidence, particularly from the fields of marketing, packaging and retail, shows that one of the main functions of a product label is as a promotional tool and the labels play an important role in influencing consumer choice.

"*Packaging has two functions: to protect and contain the product; and as an interface to sell the product to the end-user*" (Sara, 1990); "*The main implication for management is to understand and take advantage of packaging as a strategic weapon and marketing tool for the entire business, especially within a highly competitive food industry*" (Rundh, 2005).

Research shows that consumers form opinions about products based on the appearance of their packaging and label. Conjoint analysis of consumer responses to packaged food in Bangkok has shown the importance of graphics, colour, and placement of visual elements on consumer likelihood to buy - "*Quality judgments are largely influenced by product characteristics reflected by packaging, and these play a role in the formation of brand preferences" (Silayoi & Speece, 2007). Further empirical evidence has shown that visual elements of a product label, such as an image of the product itself, can be very influential at the point of sale.*

Package designs that include an aesthetically pleasing picture may enhance the strategic positioning of a brand (Underwood, Klein, & Burke, 2001).

Even government authorities acknowledge the link. Canadian Food Inspection Agency Labelling Legislative Framework explicitly denotes product promotion as a function of labels: "*Purpose of Food Labelling. Food labels represent an important, direct means of promoting a product and communicating information about that product from seller to buyer. It is one of the primary means by which consumers differentiate between individual foods and brands to make informed purchasing choices. A label serves three primary functions:*

1. *It provides basic product information including: common name; list of ingredients; net quantity; durable life date; name and address of manufacturer, dealer or importer; and in some cases, grade/quality and country of origin.*
2. *It provides health, safety, and nutrition information including: allergen information; nutrition information such as the quantity of fats, proteins, carbohydrates; vitamins and minerals present per serving of stated size of the food (in the Nutrition Facts table); specific information on products for special dietary use; and instructions for safe storage and handling.*
3. *It acts as a vehicle for food marketing, promotion and advertising via: label vignettes, promotional information and label claims such as low fat, cholesterol-free, high source of fibre, product of Canada, natural, organic, no preservatives added, and so on."*

If we specifically consider the products under discussion in this standard, there is a body of research that clearly shows that mothers and caregivers are confused by the packaging of the various stages of

breastmilk substitutes (Berry, Jones, & Iverson, 2012, 2010; Cattaneo et al., 2015; Smith & Blake, 2013). Evidence shows that follow-up formula and so called growing-up milk advertisements are perceived by mothers as promoting infant formula (Berry et al. 2010; Smith & Blake 2013; Cattaneo et al. 2014), and that the three products, are seen collectively as 'formula' (Berry 2012a). In the United Kingdom for example, 40% of women surveyed (n=2000), believed that there were no differences between the three different categories (NOP World 2005). This perception is largely attributed to the marketing practice of 'line extension' and a focus on 'brand advertising', resulting in infant formula, follow-up formula and growing-up milk appearing similar or the same to consumers.

Of additional concern is that even in cases where written information is also presented on labels, images can prove to be highly influential in consumer perceptions. This can have negative consequences for infant and young child feeding, as evidenced by the Bear Brand coffee creamer misuse as a result of a mother and baby bear illustration on product labels in Laos.

"*The cartoon logo influences people's perception of the product that belies the written warning 'This product is not to be used as a breast milk substitute.' Use of this logo on coffee creamer is misleading to the local population and places the health of infants at risk"* (Barennes, Andriatahina, Latthaphasavang, Anderson, & Srour, 2008).

Research carried out by HKI in 4 countries (Senegal, Tanzania, Cambodia and Nepal) and published in the Maternal and Child Nutrition Journal this year, also showed a range of inappropriate practices occuring on the labels of follow-up formula and growing-up milk, and in the conclusion highlighted the need for normative bodies to provide detailed guidance to prohibit practices whereby follow-up formula and growing-up milks, marketed for the age range 6-24 months, can be compared even indirectly to infant formula (Pereira et al., 2016).

Codex in carrying out its mandate to protect consumer health must pay attention to the design, images and content of labels which can influence infant and young child feeding decisions, promote inappropriate use, and potentially negatively impact on infant and young child health. This standard must make specific reference to both WHA 69.9 and the associated WHO guidance (which automatically supersedes others as is based on the latest evidence) 'Guidelines on Ending the Inappropriate Promotion of Foods for Infants and Young Children.'

4. NAME AND DEFINITION 2.1.1

We do not believe that it is a problem to repeat text from the Scope in the definitions section and in fact note that this precedent has been set within the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72 – 1981). We recommend that the text for 2. Description, 2.1 Product Definition includes text on the role, to read as follows:

2.1.1	[Follow-up formula for older infants means a product intended for use **as a substitute for human milk in helping to meet the normal nutritional requirements of older infants** ~~as the liquid part of the diet for older infants~~ when complementary feeding is introduced.] [~~Follow-up formula for young children OR [(name of product)]~~[**Fortified milk**] ~~OR [Processed milk product]~~ for young children means a product intended for use **as a substitute for human milk in helping to meet the normal nutritional requirements of young children** as ~~a liquid~~ part of the progressively diversified diet.
2.1.2	Follow-up formula [for older infants and ~~(name of product)~~ **fortified milk** for young children ~~[is]~~ [are] 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.

Rationale:

We believe that the definitions (2.1.1) should include the role of the products in order to avoid any confusion with other related standards and to ensure alignment with the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and the Guidelines on Formulated Complementary Foods for Older Infants and Young Children.

We believe that the name given to the product targeted for children 12-36 months should be significantly different to that used for the 6-12 month age group product (which can be called follow-up formula) and should not include the word 'formula'.

We believe that the evidence points to the need to give different names to the 2 products now included in this standard – one for older infants and the one for young children in order to protect consumers. The definition of infant formula in the Standard for Infant Formula and Formulas for Special Medical

Purposes Intended for Infants defines in 2.1 infant formula as meaning "*a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding*". Thus the term 'formula' has become synonymous with a product that meets normal nutritional requirements of infants, older infants and young children.

We thus strongly suggest the product for young children should have a different name that does not include the word formula, since it does not provide by itself the normal nutritional requirements of the target group aged 12-36 months. The use of the word 'formula' would be misleading, and the product could potentially be fed incorrectly as a complete replacement for all foods.

In addition, the Merriam Webster dictionary defines formula as "*a (1): recipe (2): prescription b: a milk mixture or substitute for feeding an infant.*" Thus based on both common usage of the word and the Codex definition of infant formula, a formula has become considered as meeting the normal nutritional requirements of the young infant (<6 months of age).

Functionally, any milk product for the 6-36 months age group will be used alongside other foods, displacing the consumption of breastmilk. Milks targeted at this vulnerable age group must be differentiated from infant formula to avoid misleading consumers and more importantly potentially causing negative health outcomes.

We also note that translations of the terms used for 'infant formula' show that in the many commonly used languages (French, Spanish, Portuguese, Chinese, Arabic, Hindi, Bengali) the term for 'infant formula' either includes infant, formula or like mother's milk: Leche Maternizada, formula infantile - (Spanish); Lait Maternisé (French); Fórmula Infantil (Portuguese)l Yīng yòu'ér (Infant) nǎifěn (dried milk) 婴幼奶粉 (Mandarin Chinese); aarambhik phaarmoola (baby formula) (Hindi); halib 'atfal أطفال حليب (baby milk) (Arabic); শিশু সূত্র Śiśu Sutra (infant formula) (Bengali). Thus 'baby' (the age range of 0-12 months) is commonly used with the word 'formula', but 'child' (potentially older than 12 months) is not combined with the word 'formula'.

In contrast to the current Follow-up Formula Standard, which was nutritionally suitable for older infants, the nutrient content of the now two proposed follow-up formula products differ substantially and thus should have distinctly different names and clear definitions in order to ensure that they are easily distinguished from each other and thus avoid any potential consumer misinformation.

This need for differentiation is further substantiated by research from the Helen Keller International Assessment and Research on Child Feeding (ARCH) Project, published in the Journal Maternal & Child Nutrition, that clearly showed that the manufacturers market these two products and infant formulas with the same/similar names, labels, designs, colors, and messages (paper available through open access at http://onlinelibrary.wiley.com/doi/10.1111/mcn.12269/epdf). Based on the proposed significantly different composition, it becomes necessary for the consumer to easily be able to differentiate between the 2 products under discussion.

5. LABELLING 9.

General Comments

We do not believe that the labelling requirements should be different between the 2 categories of products that this standard encompasses. We also believe that the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants should form the basis of the layout and text in this standard.

Specific Comments

5.1 SUB-HEADINGS

We support the view that section 9. 'Labelling' should include the following sub-headings:

9.1 The name of the ~~food~~ [product]

9.2 List of ingredients

9.3 Declaration of nutritive value

9.4 Date marking and storage instructions

9.5 Information for ~~utilization~~ [use]

9.6 Additional [labelling] requirements

Rationale:

The current standard is outdated and the Committee has agreed to, as far as possible, align all the standards pertaining to products for infants and young children. We believe to this end the lay-out of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants is the most relevant to follow.

5.2 REFERENCE TO RELEVANT CODEX STANDARDS/GUIDELINES

Under the section 9. 'Labelling' we propose that it is appropriate to make reference to other relevant Codex standards. We recommend that the text that be included read:

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

Rationale:

The Committee has agreed in principle that the various standards related to foods for infants and young children should, as far as possible, be aligned. It is therefore appropriate to use the text contained in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and for the following to be referenced: Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985); the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985); the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).

It is our opinion that the issue of content, nutrition and health claims has been addressed in normative global guidance and is NOT considered to be appropriate for breastmilk substitutes and should therefore not be permitted.

5.3 NAME OF THE ~~FOOD~~ PRODUCT 9.1

We believe that this text can be adapted from both the current Follow-up Formula Standard and the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants depending on which is most relevant for the products under consideration and including the 2 categories.

We recommend the current 9.1.1 should be expanded to include a new 9.1.2 and propose the following text:

9.1 The Name of the Product

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

9.1.2 The name of the product shall be either 'Follow-up Formula for older infants' or '[Fortified milk for young children]' based on the composition of the product. In addition thereto, any appropriate designation may be used in accordance with national usage.

Rationale:

We believe it is relevant for 9.1.1 of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, relating to appropriate language, to be included.

As we have indicated in our rationale under NAME AND DEFINITION 2.1.1, these products' names and terminology are highly language specific and it is critical that mothers/caregivers understand which product is appropriate for which age group.

We support the current 9.1.3 following the text in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, namely:

To be added to 9.1:

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

We believe that the current 9.1.2 and 9.1.4 cannot yet be determined until the composition is finalised.

5.4 LIST OF INGREDIENTS 9.2

We agree that 9.2.1 and 9.2.2 of the Standard for Infant Formula and Formulas for Special Medical Purposes can be adopted for both product categories.

5.5 DECLARATION OF NUTRITIVE VALUE 9.3

We support adopting the 9.3 text of the Standard for Infant Formula and Formulas for Special Medical Purposes to ensure alignment. We believe this is of particular importance across the three categories to allow mothers/caregivers to be able to make direct comparisons and not to be misled due to different presentations of this important information.

5.6 DATE MARKING AND STORAGE INSTRUCTIONS 9.4

We support adopting the 9.4 text of the Standard for Infant Formula and Formulas for Special Medical Purposes to ensure alignment.

5.7 INFORMATION FOR ~~UTILIZATION~~ USE 9.5

We strongly support adopting the text of 9.5 from the text of the Standard for Infant Formula and Formulas for Special Medical Purposes to ensure alignment. We believe that all the information is both relevant and necessary considering that the target group for these products (6 – 36 months) is highly vulnerable and must be protected from any possibility of inappropriate use of such products.

5.8 ADDITIONAL REQUIREMENTS 9.6

We strongly recommend that the text in 9.6 be altered to read:

[9.6 Additional [Labelling] Requirements:

~~The products covered by this standard are not breast-milk substitutes and shall not be presented as such.~~

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

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

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

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

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of the product.

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

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

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, fortified milks for older children and formula for special medical purposes. This includes, but is not limited to, using the same logos, icons, color schemes or terms such as 'stage 1,2,3']

Rationale:

In addition to WHA 69.9 and the associated guidance, it is clear from research that both of the categories of these products are positioned and promoted as breastmilk substitutes. For example many manufacturers commonly use a No 1 on the labels of their infant formula, a No 2 on their follow-up formula for older infants 6 -12 months and a No 3 on their product for the young child 12 – 36 months. Although different companies might take a slightly different approach, they clearly position these as a single category made of sub-sets and all are breastmilk substitutes. See the research under taken by the Helen Keller International Assessment and Research on Child Feeding (ARCH) Project results published in a supplement of the journal Maternal & Child Nutrition (April 2016 – Volume 12, Supplement 2), specifically Pereira et al. 'Cross-sectional survey shows that follow-up formula and growing-up milks are labelled similarly to infant formula in four low and middle income countries (available open source access at http://onlinelibrary.wiley.com/doi/10.1111/mcn.12269/epdf).

We strongly believe that these products ARE breastmilk substitutes. The reasons have been provided in our earlier rationale under our comments on 1. NAME OF THE STANDARD; 2. PREAMBLE; 3. SCOPE (with particular reference to the 'Labels as a promotional tool').

It is therefore critical that in the interests of fulfilling its mandate of providing consumer health protection, these products are clearly defined as being breastmilk substitutes and thus may not be promoted.

It would be totally unacceptable for this standard not to ensure that it is in line with the decision made by the World Health Assembly in May this year. Just as the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72 – 1981) has recognised the International Code of Marketing of Breastmilk Substitutes and that the products under the standard must comply, so too must this standard based on WHA 69.9 and the latest WHO Guidelines for Ending the Inappropriate Promotion of Foods for Infants and Young Children.

The proposed text provided has been adapted from the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72 – 1981) so as also to ensure alignment between the various Codex standards dealing with products for infants and young children.

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IBFAN - International Baby Food Action Network

General comments:

- Since poor diet and lack of breastfeeding is recognized to be the biggest underlying cause of ill health, disease and mortality globally ensuring that the marketing of processed packaged foods does no harm is a major challenge for all governments. Early life feeding, the protection and support of breastfeeding and sound complementary feeding are a particular concern. Codex must help not hinder government's efforts to address these issues.
- IBFAN is of the opinion that when a breastmilk substitute is medically needed, infant formula is an alternative to breastmilk for infants 0-12 months and beyond and believes the standard for any fortified milk product marketed from 6-12 months should align with the Infant Formula Standard.
- Follow-up formulas are **not necessary** as stated in WHA resolution 39:28: (b) *"the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks")*. This must be included in the scope and the labelling provisions of this standard to enable member states to include this into their national policy and regulations to give meaning to the International Code and WHA resolutions.
- WHA Resolution 69.9 has welcomed the *Guidance on ending the inappropriate promotion of foods for infants and young children* [Guidance] (WHA69/A69_7Add1). Recommendation 2 of the WHO Guidance clearly states that *"Products that function as breast-milk substitutes should not be promoted. **A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and children up to the age of 3 years (including follow-up formula and growing-up milks)**. It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products."* [7]
- The Guidance also "*applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of six month to 36 months."*
- IBFAN is of the opinion that products intended for children 1-3 years should be labelled as **fortified milk product** to avoid confusion and to ensure that families are not misled into using a product that will not meet the energy and nutrient needs of infants inappropriately. The International Code, subsequent relevant WHA resolutions and the Guidance will apply to the product regardless of name or composition if it is marketed to children up to the age of 36 months.
- It is essential that there is policy alignment between Codex instruments and the norms, standards, resolutions and recommendations adopted by the World Health Assembly, especially those relating to infant and young child feeding. This is essential for the protection of optimal infant and young child health and to support WHO infant and young child feeding recommendations. The decisions made at the WHA by Member States need to be imbedded into Codex standards and national legislation. Any Codex standard covering products targeted to children under 36 months must at the very least conform to WHA Resolution 69.9 and WHO's Guidance.

  Optional ingredients should not be permitted as these open the door for promotional nutrition and health claims that idealize these products. If there is ***relevant convincing / generally***

[7] http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf
http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf

accepted scientific evidence that ingredients are needed they should be mandatory for all products.

- **Nutrition and health claims should not be permitted** for these products. Claims idealize products that may be nutritionally inferior, and can undermine sustained breastfeeding, leading to increased non-communicable diseases, in particular obesity and dental caries.
- **Cross-branding** It is well documented that the marketing of products that function as breastmilk substitutes undermines both exclusive and continued breastfeeding. The labels of products act as a form of marketing and the labelling of fortified milk products regularly use cross-branding across the various "stages" of products. WHO's Guidance identified cross-branding as inappropriate marketing to infants and young children that should be prohibited. Products targeting children 12-36 months should not be cross-branded with infant formula that is marketed for infants.
- The **determination of the nutrient content and energy density of these products is arbitrary**. Cultural and individual complementary feeding diets vary greatly and therefore it is impossible to have a one size fits all product. **Individual needs vary from child to child** depending on the amount of breastmilk consumed and the complementary foods consumed. Where reference is made in the standard to evidence from European babies alone, this may be wholly inappropriate to infants in other parts of the world.
- There should be **no flavourings and colourings in these products**. Flavourings and colours make them appealing to children and distort the development of taste preferences. Flavours and colours are marketing tools.
- The standard should clearly and unequivocally state that lactose should be the carbohydrate of choice in any fortified milk for children. The use of other added sugars risks the development of preference for sweet foods at a young age and the development of obesity and dental caries. Since these products are not necessary or suitable as Foods for Special Medical Purposes there is no need to replace lactose for medical reasons. It is essential to set an upper level of energy derived from added sugars other than lactose.

Comments on the Recommendations:

Recommendation 14

We endorse the need for a maximum carbohydrate standard for fortified milk product.

If any sugars are added other than lactose they should not contribute more than 5% of the energy in any product.

Recommendation 21

[Fortified milk product] OR [Processed milk product for young children] OR [Follow-up formula for young children] [means a product **THAT IS NOT NECESSARY BUT MAY BE USED AS A PART OF A CHILD'S PROGRESSIVELY DIVERSIFIED DIET. IT SHOULD NOT SHARE BRANDING WITH INFANT FORMULA NOR BE PROMOTED, SINCE THIS WOULD UNDERMINE BREASFEEDING AND THE CONSUMPTION OF CULTURALLY APPROPRIATE AND MORE NUTRITIOUS BIO-DIVERSE FAMILY FOODS.**

DELETE the last sentence: *means a product intended for use as a liquid part of the progressively diversified when nutrient intakes may not be adequate to meet the nutritional requirements of young children.*

***[Follow-up formula for older infants** means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced, and*

***[Fortified milk product]** OR **[Processed milk product for young children]** OR **[Follow-up formula for young children]** [means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.]*

IDF - International Dairy Federation

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

Response to recommendation 1

IDF does not agree with the chair's proposal to set the maximum level of protein requirement for older infants at 3.0g/100 kcal. IDF continues to advocate for a maximum protein level of 3.5 g/100 kcal and reiterates its previously submitted comments justifying this approach.

Scientific evidence is core in establishing the revised Codex Standard for Follow-Up Formula for older infants. Establishing the upper protein level for follow up formula for older infants requires assessment of the totality of scientific evidence regarding safety and suitability of the maximum proposed protein level. Neither EFSA (2014) nor WHO/FAO (2007) established an upper safe limit for protein for older infants, as there was insufficient evidence to guide this.

The maximum proposed protein limit of 3.5 g protein/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). We further note that:

- Maximum protein values proposed for follow-up formula for older infants are extrapolated from minimum protein requirements, rather than from specific clinical data in older infants supporting safety and suitability of the upper protein levels.
- 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 the above 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".
- The WHO/FAO (2007) also emphasizes that "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".
- A maximum protein level of 3.5 g/100 kcal would provide 14% of total energy from protein, which is aligned with European and North American data. Indeed, European data indicated that the range of protein typically consumed by 6-12 month old infants varies between 10-15% of total energy (Lagström, 1997; Noble, 2001; Hilbig, 2005; de Boer, 2006; DGE, 2008; Fantino, 2008; Marriott, 2008; Lennox, 2013; EFSA, 2014). Similarly, US data (Butte, 2010) reported that protein intake as a percentage of energy increased with age and were within the recommendations by the Institute of Medicine (2002) for acceptable macronutrient distribution range (AMDR) of 5-20% of energy.
- We Note the results of a recent systematic review of protein levels of formula for infants in Europe (Patro Golab et al, 2016) that found limited evidence in support of the proposed relationship between protein intakes in infancy and later risk of childhood obesity, and concluded that evidence was insufficient for assessing the effects of reducing the protein concentration in infant formulas on long-term outcomes. The one randomized controlled trial that supports the early protein hypothesis (Koletzko et al. 2009) tested a Follow-Up Formula for older infants at a higher protein level (4.4g/100kcal) than is being proposed at 3.5g/100kcal.
- Considerations should be given to the diversity of protein intakes across the globe in establishing the maximum protein level, which should enable to both protein intake of older infants living in developed and developing countries. As reported in CX/NFSDU 14/36/7 2014 "It is acknowledged that some sub-groups of the population will be at risk of protein deficiency in resource limited settings, and that the dietary surveys have generally only measured protein quantity and do not provide insight as to the quality of protein in the diets of older infants and young children.".
- Average protein intakes in the majority of developed countries meet protein requirements, noting that average intakes do not reflect population intake distribution data (Gibney 2004) and therefore are not suitable to identify those with intakes below recommended levels. More limited data is available from developing countries. Surveys in Philippines, Vietnam, Malaysia, Indonesia indicate average intakes of older infants meet protein requirements, however a significant proportion still did not meet local NRVs (noting comparison to WHO protein safe levels was not published).

This data indicates there is continued benefit and a need for products to remain on the market with a protein density of 3.5g/100kcal. Adequate protein quality is particularly important for children consuming complementary diets that contain little animal protein or when quality of other protein sources may be limited. As acknowledged by WHO (2005), populations with predominantly plant based diets would benefit from higher intakes of high quality protein, reflected in the recommendation for higher milk

consumption. It is therefore important a global FuF Standard continues to encompass a range of products and cater for global nutrition needs.

Regarding footnote 2

IDF supports the proposal of the chairs to remove the square brackets around the nitrogen conversion factor for soy products and to align this footnote in the Standard for Follow-up Formula for 6-12 months (CODEX STAN 156-1987) with that in the Standard for Infant Formula Standard and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981).

This is consistent with the findings of a recent review of the scientific literature[8,9] which concluded that for soy protein products scientific publications based on experimental and/or theoretical analysis of NCFs consistently demonstrate that use of an NCF of 6.25 is incorrect and scientifically flawed. In contrast, the factor 5.71 is closely aligned with those reported in the scientific literature.

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

In the process of standard development, it is important to consider how these products are used by the consumer and subsequently what role the products will play in the overall diet which includes:

- as a replacement for milk products recommended in food based dietary guidelines that would otherwise be consumed
- as an extra food to ensure nutrient needs not readily provided by the broader diet are met
- a mix of milk product replacement and extra foods
- Given the broad range of ages and nutritional needs that products will be formulated for under this Standard, it is important the Standard allows for flexibility

Milk is recognized as an important part of a healthy diet for young children with >40 countries recommending its consumption (FAO, 2013). WHO specifically recommends in feeding guidelines for the non-breast-fed child age 6-24 months "If adequate amounts of other animal-source foods are consumed regularly, the amount of milk needed is ~200-400 mL/d; otherwise, the amount of milk needed is ~300-500 mL/d", acknowledging the important role that milk plays in growing children's diets (WHO 2005).

As such, consideration of milk macronutrient %/density, and energy density, form an important basis to help guide development of the Standard. IDF is supportive of macronutrient ranges/ density/ % that allows for that in milk (e.g. energy & fat), noting that whole milk is recommended as an important source of fat for children up to two years of age, and for those who wish reduced fat milk may be consumed from 12 months of age (while skimmed milk should not be given in the first 2 years of life) (WHO 2005).

It is important therefore that minimum levels of such nutrients are mandated to reflect minimum levels present in cow's milk

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

Response to recommendation 9

IDF support the chair's recommendation as the range for the energy density of follow-up formula for young children should accommodate the energy content of whole cow's milk, which WHO recommends as an important source of fat in the first 2 years of life of non-breastfed children (WHO, 2005). As the Standard covers an age range up to 36 months the appropriate range of energy density needs to be considered for all age >24months. Therefore IDF supports a minimum energy level of 45kcal/100mL and a maximum of 70kcal/100mL which encompasses the energy range of reduced fat milk (1.5% fat) and whole milk.

Response to recommendation 10

IDF supports the chairs proposal to have a flexible standard. We would also supports the Chair's proposal that the 'additional option' for minimum protein and fat levels be stipulated within the standard,

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[8] IDF Bulletin 482 (2016). Evaluation of nitrogen conversion factors for dairy and soy. http://store.fil-idf.org/product/bulletin-idf-n-482-2016-evaluation-nitrogen-conversion-factors-dairy-soy/

[9] Maubois, J.-L. & Lorient, D. (2016). Dairy proteins and soy proteins in infant foods nitrogen-to-protein conversion factors. J. Dairy Sci. Tech. 96, 15-25. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4701760/
Both publications are available free of charge.

however further considerations are needed regarding the proposed levels for these nutrients. Finally we also agree with the proposition to limit the carbohydrates level to 12 gram per 100kcal. As this support a quality balanced follow-up formula products and is supportive of the science of cow's milk in growing toddlers.

Minimum CHO

IDF strongly agrees with the Chairs' conclusion that no minimum carbohydrate level is required. It is not necessary to mandate a minimum level for a nutrient that is naturally occurring from the milk ingredients used in such formulations, when CHO intakes are not limited in a young child's diet and needs are met by a range of foods in the progressively diversified diet.

Maximum CHO

As already mentioned IDF agrees with the Chairs' recommendation of setting a maximum carbohydrate level at 12g per 100kcal.

These levels will restrict excess added sugar and added refined carbohydrate ingredients to such products. Excess intake of both are a concern for public health and are not in line with dietary recommendations which focus on intakes of healthy carbohydrates (wholegrains) and limiting refined CHOs. Consumption of poor-quality carbohydrates is associated with long-term weight gain, diabetes mellitus and CVD (Mozaffarian 2016). A growing body of evidence suggests that diets high in refined sugars and grains have detrimental effects on several metabolic variables, including insulin sensitivity. Evidence from prospective cohort studies and RCTs suggests that diets rich in refined carbohydrates, particularly those with a high glycaemic index, elevate risk of type 2 diabetes (Make & Phillips 2015).

The chairs also note that a maximum level of 12g/100kcal may allow for a formulation to be either low-protein or low-fat, but not both. Protein and fat both affect the GI of a product, with higher levels of both nutrients reducing the GI (Venn and Green 2007). A product that is low in both protein and fat is therefore likely to lead to a more detrimental glycaemic response. In addition to a higher GI due to lower fat and protein levels, a higher amount of carbohydrates (in particular of carbohydrates with a high GI, such as refined starches and maltodextrins) in a product with minimum fat and protein levels would significantly add to the total glycaemic load of the formulation. A formulation with moderate CHO levels and moderate protein and/or fat levels is likely to have a more beneficial effect on the glycaemic response to a formulation.

A survey of YCF in Malaysia and Indonesia, which revealed excess addition of refined added carbohydrate ingredients and added sugars to YCF resulted in high GI levels of 60-70, some with a GI >100, similar in the GI (and insulin response) of sugar sweetened soft-drinks. In contrast, YCF products formulated predominately based on milk (with a protein:CHO ratio similar to that of whole milk) and limited added CHO ingredients had similar GI and insulin responses to that of whole milk, which is low GI (Brand-Miller, 2013).

According to an international expert group there is convincing evidence that low GI/GL diets are associated with several health benefits, including a reduced risk of type 2 diabetes and coronary heart disease (Augustin et al. 2015). Low GI/GL diets may also be associated with better weight management (Augustin et al. 2015). The expert group concluded that reducing postprandial glycaemia is recognised as a beneficial physiological effect, and that ways to reduce postprandial glycaemia include slowing carbohydrate absorption by consuming low GI and low GL foods (Augustin et al. 2015).

IDF believes that even if minimum protein and fat levels were to be set, simply setting the carbohydrate level of YCF based on these levels (i.e. residual energy) is not appropriate in light of a product that is low in both protein and fat, and consequently high in (largely refined) carbohydrates, likely having a detrimental effect on glycaemic response and consequently metabolic health.

We would also supports the Chair's proposal that the 'additional option' for minimum protein and fat levels be stipulated within the Standard, however further consideration is needed for the proposed minimum protein level of 1.8g/100kcal. We do not support the proposed minimum fat level of 4g/100kcal, and continue to advocate that this minimum fat level should be 3.5g/100kcal. Younger children are recommended to consume whole milk, however from 2 years of age reduced fat milk options may also be offered. Thus it is appropriate that the minimum fat levels in these products should also cover reduced fat milk.

Minimum Protein

IDF considers it important that minimum protein levels are established in the Standard. Protein is essential for growth & development, and milk is an important source of high quality protein in young children's diets. As the product may replace milk in the diet, the substitution of milk with a product without

adequate protein levels could negatively impact the ability to meet protein requirements, and may therefore impact growth & development.

Maximum Protein

IDF supports the Chair's view that it is not necessary to include a maximum limit for protein, and as highlighted in the Chairs comments this would be out of step with current dietary guidelines, which encourage milk consumption for young children, to further restrict addition of core milk ingredients to GUMs formulations through the use of any maximum protein limit that is less than the protein density of cow's milk, as cow's milk is widely recommended for consumption for this age group (FAO, 2013) and such products may be used in the diet as a substitute for cow's milk consumption (Alexy & Kersting, 2003).

We note that maximum levels of protein are self-limiting based on the proposed energy maximum of 70kcal/100mL, and proposed maximum CHO limit.

However, we are not opposed to retaining the status quo within the Standard of a protein maximum of 5.5g/100kcal, noting this encompasses the ~average protein density of whole cow's milk, and therefore formulations predominately based on cow's milk ingredients with other added core nutrients within scope.

Further detailed rationale in support of our protein position is outlined in our July eWG comments, including consideration of the globally diverse protein intakes/ quality of this age group, where population intake distribution and not just average intakes must be accounted for, as well as the lack of UL and absence of any safety concerns with such protein levels.

Response to recommendation 11

IDF agree it is important to define minimum protein quality requirements within the Standard, however does not agree with the Chair's proposal for protein quality. IDF recommends that the requirement for minimum protein quality within the 12-36month compositional requirements should instead read as follows;

[For an equal energy value the formula must contain an available* quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (6-36month Reference pattern highlighted in Annex I]

* ***Available amino acids determined by ileal amino acid digestibility as recommended by FAO 2013 where data is available, or alternatively, true faecal crude protein digestibility where it is not***.

Rationale

IDF recommend the use of an age appropriate amino acid reference pattern that represents the requirements of young children, as defined by FAO (2013), to define protein quality within the FUFYC Standard.

To ensure the FUFYC meets the appropriate level of amino acids, it is important to adjust the dietary protein for the availability of its amino acids, which defines the digestibility, the chemical integrity and the lack of metabolic interference to ensure the FUFYC delivers the appropriate level of amino acids to the infant. The preferred methodology to measure available amino acids is the ileal digestibility amino acid method as recommended by the FAO 2013. The expert consultation convened by Moughan and colleagues (2012) compiled the available ileal digestibility data for a range of common foods and food ingredients, with additional data having been published in the interim (Rutherfurd et al, 2015). Where ileal digestibility data is not published, values for available amino acids from the protein source should be calculated using faecal crude protein digestibility values, as recommended by FAO 2013, and applied to the FUFYC minimum amino acid content. Therefore the calculation for available amino acids in the protein source is as follows;

Available amino acids = mg amino acid in protein X digestibility factor for the same amino acid

As the FAO (2013) amino acid reference scoring pattern is given as mg available amino acid per g protein requirement, and FUFYC protein content is defined per 100kcal, further calculation of minimum amino acids per 100kcal are required. The calculation is derived from the minimum protein level in order to set a minimum level of amino acids required for a 100kcal energy unit. For example, the FAO (2013) amino acid reference pattern for young children defines that 20mg histidine/g protein. If the minimum protein level in a FUFYC is set, for example at the Chair's recommendation of [1.8g] protein/100kcal then;

20mg histidine/g protein x[1.8g] protein/ 100kcal minimum protein in Standard= 36mg histidine/100kcal is required to be met by the FUFYC

This is similar to the calculation of the amino acid energy content (however with a different reference protein - breast milk) in Annex I of the IF & draft FO Standard. Protein ingredients that have a protein quality score of <1 (for example soy protein isolate has a score of 0.9 as outlined in Rutherfurd et al, 2015), then a slightly higher minimum protein level of 2g/100kcal in the FUFYC would be required to meet the minimum amino acid levels.

IDF note that the Chair has suggested defining protein quality as >85% of casein. However, without stipulation of a method, it is likely protein quality would still then defer to PER which is not appropriate[10]. The Protein Efficiency Ratio (PER) has previously been used to determine protein quality, but this is an old method and has not been considered gold standard for over 40 years. The PDCAAS on the other hand is still widely used, however, is only applicable to children above age 2 years and so excludes a key stage of young childhood covered within the FUFYC Standard. Both these methods are not suitable for all young children nor for inclusion in the FUFYC Standard as a measure for protein quality. Thus IDF recommends a more appropriate reference pattern that represents the requirements of the young child, such as the 6-36month reference pattern as recommended by FAO 2013 is considered.

Response to recommendation 12

As elaborated upon in our July submission, IDF's preference was to not have an ALA minimum and noted only an Adequate Intake had been set for the nutrient ((derived from lowest estimated mean intakes in population groups were overt ALA deficiency symptoms were not seen, EFSA, 2010), there was limited evidence that global dietary intakes were insufficient in young children, or the health effects of intakes being low relative to the AI, and thus on this basis it did not consider it met overarching principles guiding mandating this nutrient in the Standard.

IDF however acknowledges the there was some support for the Chair's proposal of a minimum ALA level within the Standard. IDF outlines below the growing body of evidence of the positive role of dairy fat in early life nutrition, such as its impact on neonatal gut maturation (Le Huerou-Luron et al., 2014; Bourlieu et al., 2015) and its favourable LA:ALA ratio for promotion of DHA synthesis in tissues.

Background

The essentiality of ALA consists of its role as a precursor for EPA and DHA. From the few cases of n-3 PUFA deficiency reported in the literature it was concluded that 0.2 E% of ALA were sufficient to increase deficient plasma levels of EPA, DPA and DHA, but not of ALA, and that this intake stimulated growth in growth-deficient children. From the same case reports "minimal" and "optimal" intakes of n-3 LCPUFA were calculated, 100 to 200 mg per day and 350 to 400 mg per day, respectively (Bjerve et al., 1987 and 1989). Mean ALA intakes in the European population are 0.7 to 0.9 g per day (0.5 E%) in young children.

Breastmilk and vegetable oils contain considerable amounts of PUFAs and LC-PUFAs, whereas cow's milk contains small amounts of PUFAs and limited LC-PUFAs (Dror and Allen, 2011). However, the LA:ALA ratio of cow's milk is favorable and may actually promote tissue DHA synthesis (Michaelsen et al., 2007). One study comparing breastmilk, formula, and cow's milk fed to full-term infants found the highest levels of DHA in the breastfed group, but higher levels of DHA in the cow's milk than in the formula group (Courage et al., 1998).

In a study with young rats as an animal model used to establish recommendations for infant nutrition, the effect of reintroducing dairy fat into infant formulas on blood and brain levels of DHA was studied by feeding a formula containing a formula with 50% dairy and 50% vegetable oils (ALA 1.6-2.5%), a formula with only dairy fat (ALA 0.8%) or a formula with only vegetable oils (ALA 8%) (Astrup et al., 2016). The 50% dairy-50% vegetable oil formula with 1.5% ALA was more efficient to increase brain DHA than a formula with vegetable oil only at the same level of ALA and LA:ALA ratio, indicating a positive role of

[10] Protein Efficiency Ratio (PER) is a well-known method to assess protein quality by means of an animal (rat) growth model, feeding a known quantity of protein to infant animals over the course of 28 days. The score is a ratio of the weight gained relative to the protein consumed. It is typically adjusted for a controlled protein, the animal nutrition research council (ANRC) Casein, which is a hydrochloric acid casein. However, the PER is an old method and has not been considered gold standard for over 40 years. Most recent recommendations promote the use of a (chemical) amino acid scoring method, typically with correction for the bioavailability of the protein with measurement of the digestibility of the protein or amino acids.

dairy fat on brain DHA accumulation. The 100% dairy fat formula was as efficient as the formula with 100% vegetable oils, despite a 10 times lower level of ALA, and comparable to a 50% dairy-50% vegetable oil formula with 2.3% ALA. The results of this study indicated that a formula with 100% dairy fat, despite a lower level of ALA (0.8%) and a low LA:ALA ratio (3) was quite sufficient to provide required brain levels of DHA and adequate bioconversion of ALA to long-chain n-3 PUFA.

Response to recommendation 13

IDF is supportive of the Chair's proposal to continue to restrict industrial TFA within the 12-36mo Standard through use of the clause '*Commercially hydrogenated oils and fats shall not be used in follow-up formula"*.

We consider this approach to be in line with global public health, expert bodies and regulators goals in limiting TFA intakes through restriction of intakes of industrially produced TFA (Uauy, 2009, FAO, 2010, EC, 2015, FDA, 2015), and consistent with guidelines that recommend milk consumption for young children (FAO, 2010, WHO, 2005).

As recognised by the Chair, skim milk and whole milk powder ingredients contain an inherent proportion of TFA which on average ranges from 2.7g to 4.9g/100g fatty acids, with a wide range around average levels, with maximum levels greater than 7g/100g FA as outlined in Table 1 below (Benbrook et al 2014; Kleim et al 2013, Mansson et al 2001 and 2008, Rego et al (2016); Coppa et al (2013); Lock & Garnsworthy (2003); O'Donnell-Megaro (2011); Heck et al (2009). We note as TFA is presented as a % i.e. g/100g FA values, regardless of total milkfat level in skim or whole milk this proportion remains relatively constant. Milk is recognised globally as an important part of a healthy diet and therefore as a suitable base ingredient for young child formula products. To restrict the naturally occurring milk TFA levels within the Standard to a maximum that does not account for a level inherent in milk is out of step with dietary guidelines and scientific literature which highlights the health benefits of milk consumption.

Inherent milk TFA levels cannot be changed, it is only through blending with vegetable oils that levels can be reduced as a proportion of the total fat blend. While the proposed compositional requirements for ALA will require blending with some vegetable oils, manufacturers can continue to make decisions around how much vegetable oil to use based on ALA levels, rather than as a driver to decrease the proportion of milkfat and inherent TFA levels of milk ingredients.

IDF would also like to highlight, and this applies to other inherent milk nutrient levels such as calcium, b12, riboflavin, if mandating minimum or maximum levels within a Standard, and intending to account for levels present in the base milk ingredients, such values cannot be based on average levels. A proportion of milks will always have levels above or below the average, and this variability should be accounted for, along with allowance for manufacturing tolerance. Thus mean +/- 3SD, or reported min and maximum values should be considered.

Table 1; Comparison of milk Trans Fatty Acid (TFA) levels from recent literature (post 2000) with units of g TFA per 100 g total fatty acid.

Country	Source	n	TFA g/100g Total Fatty Acid				Methodology		Reference
			Mean	SD	Min	Max	Method cited	Polyunsaturated TFA included*?	
								Analysis of mono and poly TFA	
USA (organic)	retail milk	143	4.0	0.9			Y	Y	Benbrook et al (2013)
USA (conv)	retail milk	108	4.1	0.6			Y	Y	Benbrook et al (2013)
England	retail milk	60	4.9		4.3	5.88	Y	Y	Kliem et al (2013)[2]
Sweden	dairy milk	28	2.7	0.7	0.6	3.9	N	Y	Mansson (2008)
Sweden	dairy milk	54	2.5	0.3	1.3	3.5	N	Y	Mansson (2001)

								Analysis of only mono TFA	
Portugal	herd milk	3			3.97	7.52	Y	N	Rego et al (2016)[1]
Europe Wide study	Herd milk	1248	2.9		1.3	7.0	mixed	N	Coppa et al (2013)[3]
USA	Retail milk	224	3.2				Y	N	O'Donnell-Megaro (2011)
Netherlands	raw milk	52	2.3				Y	N	Heck et al (2009)
England	herd milk	36	3.3		2.6	4.5	Y	N	Lock & Garnsworthy (2003)[3]

1. Changes in bulk milk over trial of 8 cows over three periods (pasture, mixed ration and pasture).
2. Total trans calculated from values reported by subtracting CLA, only monthly means reported
3. Monthly means over 3 years. Ranges of monthly means reported

Response to recommendation 16

IDF consider the minimum levels proposed for calcium, riboflavin and B12 very low relative to the minimum levels present in whole cow's milk. We note the reason for mandating these nutrients was due to cow's milk being an important source of these essential nutrients, and displacement of cow's milk consumption could increase risk recommended requirements for young children were not met. IDF does note that manufacturers will always target levels greater than the minimum in order to ensure compliance of finished product, and that products with a higher quantity of milk (milk protein) will naturally contain levels of these nutrients at levels more comparable to that of milk.

IDF refer to the earlier submission and does not consider it necessary to mandate upper limits for these nutrients considering the absence of market failure of the current Standard and other Standard which do not mandate these upper limits, noting B12 and riboflavin do not have UL's established and for calcium it is technically difficult to 'over' fortify as this would result in product chalkiness.

IDF note the Chair's guiding principles in developing upper limits for these nutrients based on levels in cow's milk. However, Food Composition average milk values were summarised for the upper limits, and upper limits should always take account of the natural variability in milk as a proportion of milk will always sit above the average level. It is more appropriate maximum levels in milk or mean +3SD is accounted for.

SCOPE AND LABELLING

Response to recommendation 20

IDF appreciates the considerations of the eWG Chair and supports the recommendation to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. Section A will refer to the essential composition and labelling of follow-up formula for older infants, and Section B will deal with the essential composition and labelling of product for young children.

Response to recommendation 21

IDF does not support the eWG recommendation for the suggested alternative names proposed for Follow-up Formula for young children as a name specificity of the different product categories.

IDF notes that there is desire for Follow-up Formula for young children to be easily distinguishable from Follow-up Formula for older infants so as to avoid consumer confusion about the suitability of individual products for different age groups. The suggestion is that this could be achieved by using distinctly different names for the different product categories.

Our preference is to have short names that can be adopted by regulatory bodies and easily understood by consumers. Therefore, careful consideration of names is recommended in order to facilitate greater harmonisation and consistency.

Therefore, IDF suggests to amend the proposed definitions as follows:

[Follow-up formula for older infants means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced.]

~~**[Fortified milk product]** OR **[Processed milk product for young children]** OR~~ [Follow-up formula for young children] [means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children]

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Annex I: Table 1: Essential and Semi-Essential Amino Acids required for 6-36 month children*

For the purpose of this Standard the essential and semi-essential amino acids required for a 6 – 36 month child from WHO/FAO 2007, and recommended by FAO 2013, expressed as amino acid requirement per gram of protein, are listed.

The level of an amino acid (mg/g protein) is used to calculate the minimum amino acid content per 100kcal of a FUFYC. As no minimum protein content has yet been defined for the FUFYC Standard, column two shows the calculation of the minimum amino acid content (mg/100kcal), that will be used after the minimum protein is defined within the Standard i.e. mg amino acid/g crude protein multiplied by the minimum total protein defined in the Standard.

	mg/g protein*	**mg/100kcal**
Histidine	20	20mg/g x [min protein g/100kcal]= mg/100kcal
Isoleucine	32	32mg/g x [min protein g/100kcal]= mg/100kcal

Leucine	66	66mg/g x [min protein g/100kcal]= mg/100kcal
Lysine	57	57mg/g x [min protein g/100kcal]= mg/100kcal
Phenylalanine + Tyrosine (AAA)	52	52mg/g x [min protein g/100kcal]= mg/100kcal
Methionine + Cysteine (SAA)	27	27mg/g x [min protein g/100kcal]= mg/100kcal
Threonine	31	31mg/g x [min protein g/100kcal]= mg/100kcal
Tryptophan	8.5	8.5mg/g x [min protein g/100kcal]= mg/100kcal
Valine	43	43mg/g x [min protein g/100kcal]= mg/100kcal

* Adapted from FAO 2013

Annex II background on TFA

IDF reiterates the importance of reviewing whole foods and not only single nutrients in isolation when studying diet effects and considering nutrient compositional criteria within a Standard. Milk is a core ingredient in young child formula, and its consumption is associated with a number of health benefits. For example, TFA have been associated with increased risk of CVD, however the evidence is strong only for industrial TFA or when consumed in quantities highly exceeding the normal intake (up to 10 times higher). As for all nutrients, there is an intake threshold above which negative health outcomes may occur. Indeed, when ruminant TFA are consumed in typical amounts, there is a growing body of evidence that shows that dairy intake with its inherent ruminant TFA levels has no effect on CHD/CVD and may be protective (Soedamah-Muthu 2011, de Oliveira Otto et, al. 2012; Kratz et al 2012, Astrup et al., 2016). Dairy intake is also inversely associated with weight gain and the risk of obesity (Astrup et al., 2016). This must be considered when proposing any measures, such as a % TFA maximum, that could limit the amount of milk present in young child formula products.

TRANS FAT DEFINITION

Most unsaturated fatty acids in foods have at least one double bond in the *cis* configuration. Trans fatty acids (TFA) are unsaturated fatty acids with at least one double bond in the *trans* configuration, however this definition varies among countries. Some polyunsaturated TFA have conjugated double bonds, such as conjugated CLA.

TFA in foods are either:

- Ruminant TFA (rTFA) from:
    - Bacterial hydrogenation of unsaturated fatty acids in the rumen of ruminant animals (cows, sheep, goats..)
    - Meat of ruminant animals also contains TFA.
- Industrial TFA (iTFA) from:
    - Industrial hydrogenation to harden fats for the production of foods such as margarine and biscuits, and poorly-controlled deodorization of unsaturated vegetable or fish oils
    - Heating and frying of oils at high temperatures

Ruminant and industrial TFA present a large number of isomers of monounsaturated and polyunsaturated fatty acids. The main rTFA is vaccenic acid (18:1t, n-7) while the main iTFA is elaidic acid (18:1t, n-9). The TFA profiles of ruminant and industrial TFA overlap with many isomers in common but in different proportions. It is currently not possible to accurately differentiate between ruminant and industrial TFA in a food product with simple analytical methods. TFA may be measured using infrared spectroscopy (estimation of total non-conjugated TFA), gas chromatography or high pressure liquid chromatography (the latter two can measure individual TFA).

The difference in iTFA and rTFA profiles has an impact on their functional, physical and biological properties (Stender et al., 2008; de Souza et al., 2015).

Trans fat intake and recommendations

The WHO recommends a TFA intake of less than 1 % of total energy (Nishida and Uauy, 2009). The TRANSFAIR study (van Poppel, 1998) reported the mean daily intake of TFA in 14 European countries for 1995-1996, with men consuming 1.2-6.7 g/day (0.5-2.1 % of energy) and women 1.7-4.1 g/day (0.8-1.9 % of energy). Ruminant TFA contributed to 30-80 % of total TFA or 0.3-0.8 % of energy, which is less than the maximum level recommended by the WHO. With recent reformulation of industrially-produced foods, TFA intake has decreased. TFA intake in Australia (population 2 years and older) in 2006 was 1.4 g/day or 0.6 % of energy of which 60 % were rTFA and 16 % from food containing both rTFA and iTFA (Reuss et al., 2009). In New Zealand (population 15 years and older) in 2006, TFA intake was 1.7 g/day or 0.7 % of energy of which 41 % were rTFA and 13 % from food containing both rTFA and iTFA.

While the effect of ruminant TFA cannot be accurately tested as it is not possible to extract TFA from dairy fat, evidence from human intervention studies should be carefully reviewed with considerations of the type of TFA (added synthetic, naturally occurring or industrial), the studied levels vs typical consumed levels and the mode of delivery (consumed as part of a whole food or in isolation).

Jacobsen et al. (2008) recorded the consumption of rTFA in a Danish population as part of an 18-year follow-up study. In Denmark, women consumed daily between 0.5 and 3.1 g of ruminant TFA and men 0.6-4.1 g of ruminant TFA. The study suggested that rTFA intake was not associated with higher risk of coronary heart disease.

Trans fat and cardiovascular disease (CVD)

There is convincing evidence that TFA from commercial partially hydrogenated vegetable oils increase the risk factors and events of coronary heart disease (CHD) as outlined by FAO and WHO (FAO, 2010; Uauy et al., 2009). EFSA (EFSA, 2010) concluded that rTFA have similar adverse effects on blood lipids and lipoproteins as TFAs from industrial sources, when consumed in equal amounts. However, The WHO's 2009 Scientific Update on trans fatty acids suggests that the intake of rTFA is low enough in most populations not to constitute a significant risk factor.

More recently the WHO (2016) also examined the effects of industrial and ruminant TFA on blood lipids in a systematic review of 16 random clinical trials, only 4 of which were on ruminant TFA. While the evidence for an effect of reducing total and industrial TFA intake by replacement with other fatty acids or carbohydrates was high, the evidence for an effect on blood lipids of replacing ruminant TFA with cis-MUFA, cis-PUFA, SFA or carbohydrates on most outcomes was judged to be GRADE LOW (due to serious inconsistency and serious imprecision). The authors concluded that the effects observed for ruminant studies may actually have been a result of differences in dose rather than type of TFA. In addition, the number of studies on rTFA is small because it is difficult to design diets comprising natural, unmodified foods with high intakes of rTFA. This suggests that in current real-world settings, intakes of ruminant TFA are generally low, which would correspond to a small resulting risk of negative health effects. Thus the WHO 2009 opinion is still relevant.

A recent systematic review and meta-analysis commissioned by the WHO (de Souza et al., 2015) reported that industrial, but not ruminant, trans fats were associated with coronary heart disease (CHD) mortality, and CHD. From prospective cohort studies (de Souza et al., 2015), the certainty of associations of ruminant trans fat with cardiovascular disease, CHD, ischemic stroke and type 2 diabetes outcomes was “very low”. Association of trans fats with all cause mortality, total CHD and CHD mortality is probably because of commonly higher levels of intake of industrial trans fats than ruminant trans fats. However, in another review of observational studies (Stender et al., 2008), a daily intake of 5 g of primarily industrial TFA was associated with a 29% increased risk of CHD whereas no such association was found for a daily intake of 4 g of ruminant TFA. A consumption of 3.3 L of full-fat milk (3.9 % TFA and 3.1 % total fat) per day would provide 4 of of rTFA.

Case control studies (Colon-Ramos et al., 2006; Baylin et al., 2003; Block et al., 2008; Ghahremanpour et al., 2008; Park et al., 2009; Van de Vijver et al., 1996; Aro et al., 1995) have shown a strong association between trans-18:2 isomers, abundant in partially hydrogenated oils, and CHD but no significant association between trans-18:1 isomers, derived from partially hydrogenated oils and also found in ruminant foods, and CHD. In overweight women, dairy fat enriched with trans-11 vaccenic acid and conjugated linoleic acid had a neutral impact on peripheral insulin sensitivity in overweight women (Wang and Proctor, 2013). Non-conjugated trans 18:2, present in industrial TFA, have been shown to have a stronger positive relationship with CHD than for other TFA (Wang and Proctor, 2013).

In a recent double-blind, randomized, crossover study in healthy adults, Gebauer et al. (2015) investigated the effects of vaccenic acid (3% of energy) and industrial TFA (3% of of energy) on lipoprotein risk factors compared with a control diet (low TFA 0.1% of energy). Compared with control,

vaccenic acid and industrial TFA both raised total cholesterol, LDL-cholesterol, total:HDL-cholesterol ratio, and apoliprotein B. However, vaccenic acid also increased HDL-cholesterol, apolipoprotein AI, apolipoprotein B and lipoprotein (a), unlike industrial TFA. Of importance, vaccenic acid is present in both ruminant and industrial TFA, however in the study by Gebauer et al. (2015), a synthetic triglyceride containing vaccenic acid was used, differing from the form of vaccenic acid present in dairy products. It was outlined that vaccenic acid consumed in typical dietary amounts and natural forms (from foods) is inversely or not associated with cardiovascular risk. Indeed the levels tested in this study were higher (up to 10 times) than typical daily intakes from dairy products. The daily TFA intakes tested in Gebauer et al. (2015) were as follows:

- Men on a mean daily calorie intake of 2700 kcal: 11.8 g of vaccenic acid or 9.8 g of industrial TFA
- Women on a mean daily calorie intake of 2200 kcal: 9.6 g of vaccenic acid or 8.0 g of industrial TFA

As concluded by Wang and Proctor (2013) based on findings from recent prospective cohort studies and randomised clinical trials and earlier systematic reviews, moderate consumption of rTFA at typically consumed levels has no adverse effect on CVD risk. In general it has been found that rTFA has little effect of the on public health as the concentration in dairy products is low and rTFA intake contribute to less than 1% total daily energy (EFSA, 2015).

Epidemiological evidence is important. It is important to review whole foods and not only single nutrients in isolation when studying diet effects and setting nutrient limits in a standard. A growing body of evidence shows that dairy intake, including regular fat dairy intake, has no effect on CHD/CVD and may possibly be protective (Soedamah-Muthu 2011, de Oliveira Otto et, al. 2012; Kratz et al 2013, Astrup et al., 2016). Dairy intake is also inversely associated with weight gain and the risk of obesity (Astrup et al., 2016).

It is over-simplifying to rely solely on lipid biomarkers to predict CVD risk in dietary studies, as CVD is influenced by many pathways and LDL-cholesterol measurement does not necessarily reflect CVD risk (Astrup et al., 2016). The International Institute of Medicine concludes that LDL-cholesterol is an appropriate lipid biomarker to determine CVD risk for some statin (i.e. drug) interventions, but not for interventions with foods (IOM 2010). Dairy fat contains about 400 different fatty acids and dairy products are complex food matrices providing a wide range of nutrients. The assumption that consumption of dairy fat will increase plasma LDL-cholesterol and therefore the risk of CVD is too simplistic and does not take into account the biological differences between fatty acids, the structural and compositional complexity of the dairy food matrix and the multi-factorial nature of CVD (Astrup et al., 2016).

Trans fats in early life

The role of TFA in early life is poorly documented. The importance of cis versus trans fats in toddlerhood is unknown and the role of TFA in toddlerhood is extrapolated from studies in adults (Wyllie et al., 2015). As mentioned above, in vitro and animal studies suggested a negative relationship between TFA and the proportions of essential fatty acids and their metabolites in blood lipids and tissues (EFSA, 2004). An inverse correlation has been suggested between dietary TFA and the levels of LC-PUFAs in blood lipids classes in preterm infants, fetal tissues and umbilical arterial walls from term infants, and in plasma phospholipids from 1-15 year-old children (Larque et al., 2001). It was suggested that TFA impaired the elongation and desaturation processes of essential fatty acids. Many of the mechanistic studies have used models of essential fatty acid deficiency or dietary TFA intake significantly higher than typically consumed.

TFA are suggested to be transported across the placenta (Bauer and Waldrop, 2009). However the results in animal studies and humans are not consistent (Larque et al., 2001). Little amount of TFA might cross the placenta, but they might be catabolized in tissues of the fetus instead of being stored, or they might be diluted within the novo-synthesized fatty acids. A few studies have looked at the effect of maternal dietary TFA and birth outcomes and cord blood (Koletzko, 1992; Desci et al., 2001; Elias and Innis, 2001). While in preterm infants (Koletzko, 1992) a negative relationship between the proportion of TFA in plasma cholesteryl esters and phospholipids with birth weight was observed, this was not observed in full-term infants (Decsi et al., 2001). Elias and Innis (2001) did not observed either a relationship with birth weight or birth length in full-term infants, however they reported a negative relationship between the proportion of TFA in cholesteryl ester from infant umbilical cord plasma with length of gestation. It is important to note that the evidence is based on studies carried out before the reformulation of many processed foods and the subsequent high reduction of industrial TFA intake.

Using multigenerational animal models, no adverse effects of dietary TFA were observed on frowth, reproduction and longevity. (Larque et al., 2001).

TFA are present in breast milk at a level of 2 to 5 % of total fatty acids and vary as a function of maternal diet (Larqué et al., 2001; Bauer and Waldrop, 2009). Cow's milk fat is more similar to human breast milk fat than vegetable oils are, with a better proportion of palmitic acid in the sn-2 position, and similar content of cholesterol, short and medium-chain fatty acids, TFA and branched-chain fatty acids (Astrup et al., 2016). The most prevalent isomer of 18:1 in breast milk is vaccenic acid, simarly to cow's milk (Innis and King, 1999). As reported by Innis and King (1999), intake of hydrogenated oils containing TFA may result in displacement of cis n-6 and n-3 unsaturated fatty acids and adversely affect their metabolism. A high TFA diet increases the level of linoleic acid in human milk but does not impact the levels of LC-PUFAs (Larque et al., 2001). Innis and King (1999) studied the relationship between TFA content in breast milk, the maternal dietary intake of TFA and plasma lipids in breastfed infants. The mean breast milk TFA level was 7.1 ± 0.32 % of total fatty acids and the mean maternal TFA intake was 7.7 % of total fat (2.5% of total energy), with the majority of TFA being from industrial sources and less than 10 % from dairy products. Milk TFA were inversely related to milk 18:2 n-6 and 18:3 n-3.

TFA are incorporated into tissues in lower proportion than provided by the diet and preferentially in the sn-1 position of membrane phospholipids, competing with saturated fatty acids (Larque et al., 2001). Negligible to no level of TFA are incorporated into the brain, suggesting a protective mechanism to limit the incorporation of TFA in the central nervous system.

Globally public health bodies aim to reduce intakes of TFA due to its negative effects on health. Milk and milk products contain inherent TFA levels, however regulators and public health bodies alike recognise that dairy products contribute to a healthy balanced diet for young children (FAO, 2010) and provide essential nutrients (EFSA, 2015).

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ISDI - International Special Dietary Foods Industries

(i) General Comments

Follow-up Formula for older infants (6-12 months)

ISDI welcomes the progress made on finalizing the composition criteria for Follow-up Formula for older infants based on the eWG Chair's proposal and comments from eWG members. However, ISDI would like to point out some issues that require further consideration, which are highlighted below.

Follow-up Formula for young children (12-36 months)

ISDI reiterates its position from CP2 on the composition criteria for young children as follows:

Key Principles

In terms of establishing compositional requirements of Follow-up Formula for young children as a liquid part of the diversified diet, the primary objective should be to contribute to the nutritional needs of young children.

This primary objective can be achieved by considering the following; 1) effectively support the nutritional needs of young children globally, 2) address globally relevant dietary nutrient inadequacies, 3) take into account the key nutrient levels provided by cow's milk and 4) maintain the nutritional integrity of the product.

While each nutrient is assessed on a case by case basis, the compositional criteria should always take these principles into consideration.

Mandatory Composition Criteria

Based on the above, ISDI supports establishing mandatory compositional criteria for the following nutrients:

- Energy, including specification for minimum and maximum level of energy

- Protein, including specifications for minimum and maximum level of protein

- Fat, including specifications for linoleic acid, α-linolenic acid and trans fatty acids

-Carbohydrates, including specifications for maximum levels for carbohydrate and added sugars

- Vitamins and minerals: iron, calcium, vitamin A, riboflavin, vitamin B12, vitamin D, vitamin C, zinc, iodine, sodium and folic acid.

ISDI notes that the eWG has not included iodine and folic acid on the mandatory (core) list of nutrients – as proposed in the ISDI reply to CP1 and CP2. Furthermore, the eWG has not definitively recommended the inclusion of vitamin A, vitamin D and zinc on this list. ISDI asks that further consideration is given to their inclusion.

Optional Additions

ISDI reiterates its position from CP2 that a simplified approach is required and hence proposes Option 2 for the Optional Addition category. This is aligned with previous ISDI positions of supporting a principle based approach and that a third category is not required. Further elaboration is provided below in Recommendation 8.

(ii) Specific Comments

Recommendation 1

Minimum Protein

ISDI remains of the view that it would be appropriate to adopt a lower minimum protein level of 1.65 g/100 kcal and, as has previously been suggested, a footnote should accompany the protein level, to ensure that low protein levels are scientifically substantiated, and, when needed, clinically evaluated.

Maximum Protein

ISDI also remains of the view that the protein maximum should be 3.5 g/100 kcal.

Footnote 2

ISDI suggests that CCNFSDU gives further consideration on how the protein conversion factor for soy is defined and that CCNFSDU refers this discussion to relevant experts in this matter (e.g., CCMAS, CAC).

Footnote 3

ISDI agrees that minimum levels for amino acids should be included in footnote 3 using the amino acid composition of breast milk as a reference.

Footnote 5

ISDI recommends re-wording of the second sentence as follows:

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

Footnote 6

ISDI supports the inclusion of a modified footnote 6 and would propose:

[6] **Follow-up formula based on non-hydrolysed milk protein** containing **1.65-1.8 g protein/100 kcal** should be **scientifically substantiated and when needed** clinically evaluated.

Follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal should be **scientifically substantiated and when needed** clinically evaluated.

Justification:

Minimum protein

Protein requirements have been recently estimated to be lower than previous estimates primarily as a result of changes in the reference body weights used. Additionally several dietary surveys of protein intakes in older infants (6-12 months) have identified that average protein intakes are adequate and above minimum requirements for the majority of this age group. ISDI refers to the proposal by ENA, which based on the protein requirements, recommends to lower the minimum protein level to 1.65 g/100 kcal (Koletzko 2013). Safety and suitability of a formula with 1.65 g/100 kcal have been clinically evaluated in infants (Inostroza 2014, Ziegler 2015). In addition, the lower level takes into account the essential amino acids that can be delivered at this protein level. The amino acid profile for 6-12 months that should be adopted is that based on the profile of amino acids in human milk.

The full justification and references were provided in the ISDI response to CP1 in April 2016 as well as in in CP2 in July 2016.

Maximum protein

ISDI continues to support a maximum protein level of 3.5 g/100 kcal on the basis that no new scientific evidence regarding protein requirements and upper safe protein intake levels is available to establish a protein UL since the 37th session of CCNFSDU. Furthermore, protein levels of 3.5 g/100 kcal are safely available on the market today, and this protein maximum would allow overlap between the current and the revised Standards. This would support continuity of international trade and consumer trust in both current and revised Codex Standard for Follow-Up Formula. We refer to previously submitted comments in support of the scientific and general substantiation of a maximum protein level of 3.5 g/100 kcal.

Footnote 2

With respect to the appropriate nitrogen conversion factor to include for other soy protein-based follow-up formula, ISDI considers the following points to be taken into consideration: a) reference to the Codex Standard for Infant Formula (Codex STAN 72-1981), where similar discussions regarding conversion factor and minimum protein level led to compromise regarding the wording (see Codex STAN 72-1981 - 3.1.3 a) Protein), b) the conclusions of the 37th CCNFDSU Session (November 2015) requesting advice from CCMAS (Committee on Methods of Analysis and Sampling) on the accuracy and appropriateness of 5.71 as the nitrogen factor for soy protein isolates used in formula for infants and young children and c) the discussions at 37th CCMAS 37 (February 2016) where it was noted that it may be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors.

Against this background, ISDI agrees that a review of the appropriate conversion factor should be conducted by relevant experts and that CCNFSDU may not be the appropriate forum to discuss this topic. Therefore ISDI would recommend additional expert advice to enable this topic to be solved as highlighted above.

Footnote 3

Since the adoption of the Codex Standard for Infant Formula and its Annex I, new publications describing the amino acid profile in human milk (Zhang 2013, Lönnerdal 2016) should be considered. In addition, if the minimum protein level of 1.65 g/100 kcal is adopted, new calculations should be made using 1.65 instead of 1.8 currently used in Annex I of the Codex Standard for Infant Formula for calculation.

Footnote 6

ISDI considers that all formulas containing a protein content between 1.65 and 1.8 g/100 kcal should be scientifically substantiated, and when needed, clinically evaluated. This will confirm their safety and suitability. ISDI considers that follow-up formula for older infants containing a protein level between 1.8 g and 2.0 g/100 kcal do not require clinical evaluation, in agreement with a recent EFSA assessment (EFSA, 2014).

ISDI considers that hydrolysed protein has been safely used as a protein source in follow-up formula for older infants. Several studies have demonstrated that formulas based on hydrolysed protein support adequate growth of during infancy (Berseth, 2009; Vandenplas, 2016). If a formula based on hydrolysed

protein containing <2.25 g/100 kcal has been substantiated in the infant population, it is unnecessary to clinically evaluate such formulation in the older infant population, thus ISDI considers the statement 'when needed' is helpful to this clause.

Therefore ISDI proposes that footnote 6 should read:

[6)] **Follow-up formula based on non-hydrolysed milk protein** containing **1.65-1.8 g protein/100 kcal** should be **scientifically substantiated and when needed** clinically evaluated.

Follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal should be **scientifically substantiated and when needed** clinically evaluated.

References

(as mentioned in this box, further references are listed in ISDI response to eWG second consultation paper of July 2016)

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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.

Lönnerdal B, Erdmann P, Thakkar Sagar K et al. (2016), Longitudinal evolution of true protein, amino acids, and bioactive proteins in breast milk: A developmental perspective. The Journal of Nutritional Biochemistry, 2016.06.001.

Vandenplas Y, Alarcon P, Fleischer D, et al. (2016) Should partial hydrolysates be used as starter infant formula? A working group consensus. Journal of Pediatric Gastroenterology and Nutrition, 62: 22–35.

Zhang Z, Adelman AS, Rai D et al. (2013) Amino acid profiles in term and preterm human milk through lactation: a systematic review. Nutrients, 5:4800-4821.

Ziegler EE, Fields DA, Chernausek SD et al. (2015) Adequacy of infant formula with protein content of 1.6 g/100 kcal for infants between 3 and 12 months. Journal of Pediatric Gastroenterology and Nutrition, 61:596-603.

Recommendation 2

ISDI supports the eWG recommendation.

Recommendation 3

Although ISDI previously supported a minimum vitamin C level of 4 mg/100 kcal, ISDI is able to support the proposal of the eWG Chair both for the minimum and GUL levels in the sake of reaching consensus.

Recommendation 4

ISDI supports the eWG recommendation.

Recommendation 5

ISDI reiterates its position shared in CP1 and CP2, namely a) support for the optional addition of DHA, b) no specific minimum level and c) no mandatory addition of ARA when DHA is added, which is to be appropriately reflected in the footnote.

As stated in CP1 and CP2, ISDI recognizes that national authorities have established minimum levels for DHA to be added to follow-up formula for older infants solidly based on scientific assessments. Against this background, ISDI reiterates its position that, due to the variability of DHA intake in the diversified diet of older infants, the Codex Standard for Follow-Up Formula for older infants should not establish a minimum DHA level, but refers considerations regarding minimum levels to national authorities. The introduction of a footnote is recommended.

Justification:

In the ISDI position submitted to the 37th session of CCNFSDU (2015), ISDI supported the inclusion of DHA as an optional ingredient :

"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)."

In response to the request whether a minimum DHA level should be introduced into the revised Codex Standard for Follow-Up Formula for older infants (Codex STAN 156-1989), ISDI takes into consideration that several expert opinions have:

- Established nutritional requirements for DHA and concluded that the dietary DHA intake may be low in older infants (AFSSA, 2010; FAO, 2010; EFSA, 2013; Koletzko, 2013; EFSA, 2014);
- Recommended DHA intake levels associated with beneficial health outcomes (AFSSA, 2010; FAO, 2010; EFSA, 2014);
- Established minimum DHA levels for supplementation of Follow-up Formula for older infants at 0.3% of total fatty acids (AFSSA, 2010; FAO, 2010; EFSA, 2014).

Although ISDI recognizes the consistency of the expert recommendations, ISDI also emphasizes that due to the global variability of dietary DHA intakes, it remains challenging to establish a global recommendation for a minimum DHA level in the Codex Standard for Follow-up Formula for older infants.

Therefore and in conclusion, ISDI considers that no minimum DHA level should be set and recommends that considerations regarding a minimum level for DHA be referred to national authorities. The introduction of a footnote would be appropriate to accommodate national competent authorities to establish a minimum DHA level and could potentially read as follow "*National authorities may establish a minimum DHA level, as appropriate for the nutritional needs.*"

References

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

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

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

FAO (2010) Fats and fatty acids in human nutrition. A report of an expert consultation. *FAO Food and Nutrition Paper* 91. Rome

ISDI comments to 37th session of the CCNFSDU (2015) Review of the Standard for Follow-up Formula (Codex STAN 156-1987). CX/NFSDU 15/37/5-Add.1

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 6

ISDI supports the amended wording proposed for clause 1.3.2.4. ISDI also is supportive of the addition of clause 1.3.2.5 but proposes alternative wording as follows:

1.3.2.5 [The safety and suitability of the addition of specific **bacterial** strains ~~**of L(+) lactic acid producing cultures**~~ for particular~~**ly**~~ nutritional purposes~~**, at the level of use,**~~ shall be demonstrated by generally accepted scientific evidence **at the level of use**. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect. **Bacterial strains added for particular nutritional purposes may be, but are not limited to L(+) lactic acid producing bacteria.**]

Justification:

ISDI fully supports the intent of this recommendation to provide greater clarity with respect to the addition of bacterial strains and its purposes (technological function and for nutritive purpose).

The justification for the amended wording proposed for clause 1.3.2.5 outlined in the above box is as follows. Firstly, bacterial strains added to foods for particular nutritional purposes may be, but are not limited to L (+) lactic acid producing cultures. The criteria set-out for the addition of viable bacteria for particular nutritional purposes requires their safety and suitability to be demonstrated by generally accepted scientific evidence at the level of use. These requirements are in alignment with the principle-based requirements for other optional ingredients. As such, ISDI contends that it is counterproductive to simultaneously apply a limit to use of L(+) lactic acid producing cultures only. Codex standards are intended to have longevity and as such need to provide flexibility for the addition of new ingredients,

including bacterial cultures, scientifically demonstrated and assessed by expert panels and/or regulatory authorities.

Recommendation 7

ISDI supports the eWG recommendation.

Recommendation 8

Mandatory (core) composition

ISDI would like to refer to its comments made in CP2 regarding the mandatory composition of Follow-up Formula for young children.

In summary, the establishment of compositional requirements for Follow-up Formula for young children should focus on the primary objective of contributing to the nutritional needs of young children. This objective can be achieved by considering the following principles: 1) supporting effectively the nutritional needs of young children globally, 2) addressing globally relevant dietary nutrient inadequacies, 3) taking into consideration the key nutrient levels provided by cow's milk and 4) maintaining the nutritional integrity of the product.

While each nutrient is assessed on a case by case basis, the compositional criteria should always take these principles into consideration.

Hence ISDI supports mandatory compositional criteria for the following nutrients:

- Energy
- Protein
- Fat, including specifications for linoleic acid, α-linolenic acid and [exclusion of] industrial trans fatty acids
- Carbohydrates, including specifications for carbohydrates and added sugars
- Vitamins and minerals: iron, calcium, vitamin A, riboflavin, vitamin B_{12}, vitamin D, vitamin C, zinc, iodine, sodium and folic acid.

Optional additions

ISDI supports option 2 proposed for optional additions and agrees with the eWG Chair to delete the third bullet point.

This is consistent with ISDI's position in CP2. There is no specific need for special provisions to manage nutrients that are not included in the mandatory core composition but are included in the essential composition for Follow-up Formula for Older Infants.

Therefore, ISDI does not support the establishment of a third category (previous consultation papers referred to this category as 'voluntary' nutrients).

However, ISDI supports that any ingredient/nutrient already permitted and considered as safe in Follow-up Formula for older infants (6-12m) should also be permitted in Follow-up Formula for young children (12-36m) as an optional ingredient. Thus, there is no need for an additional assessment.

In addition, ISDI also points out that specifying minimum levels for non-mandatory nutrients is counter to approach used for optional ingredients listed in the infant formula standard and as proposed currently for optional ingredients for Follow-up Formula for Older Infants.

Justification:

Mandatory (core) composition

Based on the 4 key principles as described above, ISDI proposes the following mandatory composition criteria:

- Energy
- Protein
- Fat, including specifications for linoleic acid, α-linolenic acid and [exclusion of] industrial trans fatty acids
- Carbohydrates, including specifications for carbohydrates and added sugars

- Vitamins and minerals: iron, calcium, vitamin A, riboflavin, vitamin B_{12}, vitamin D, vitamin C, zinc, iodine, sodium and folic acid.

ISDI recommends that all nutrients that meet the principles for inclusion in the mandatory (core) composition are included in the mandatory composition section of this standard, including nutrients like zinc and iodine. This allows for appropriate minimum and upper levels to be applied for the target age range taking into consideration 1) the nutritional drivers, 2) levels already provided in the diet and 3) and technical feasibility. This will greatly facilitate international harmonisation of requirements and provide more appropriate guidance to regulators and industry on appropriate levels than the other options proposed.

Optional additions

ISDI supports option 2 based on the general principle that when an ingredient is recognized as safe and suitable for the target age, it could be used. ISDI is of the view that nutrients that are not included in the mandatory core composition, but are included in the essential composition for Follow-up Formula for Older Infants, do not need to be covered by special provisions (previously referred to as 'voluntary additions'). These ingredients could be covered by the optional additions principle and do not require reassessment. In fact, the level of use proposed in Follow-up Formula for older infants should be adapted to the need of young children. Underlying ISDI's rationale is that the principles that apply for optional ingredients are different to those that have been developed for inclusion in the mandatory composition.

Limits applied to nutrients for Follow-up Formula for Older Infants should not be assumed as suitable for Follow-up Formulas for Young Children as there are marked differences in gross composition possible between Follow-up Formula for Older Infants and Follow-up Formula for Young Children. The levels of some of these nutrients naturally present in Follow-up Formula for Young Children from ingredients used, may in some cases exceed the permitted levels in Codex Follow-up Formula for Older Infants and thus need to be adapted.

To summarise:

- ISDI is not aligned with the proposal put forward by the eWG for mandatory (core) composition.

- ISDI recommends adoption of option 2 proposed for optional additions which allows for optional ingredients added only in accordance with the principles specified in the optional addition section. Following this approach the third bullet point becomes redundant and ISDI supports its deletion as proposed by the eWG Chair.

However, ISDI supports that any ingredient/nutrient already permitted and considered as safe in Follow-up Formula for older infants (6-12m) should also be permitted in Follow-up Formula for young children (12-36m) as an optional addition. Thus, there is no need for an additional assessment.

Recommendation 9

ISDI continues to support its position of CP2, and therefore proposes the following amended wording proposed for clause 3.1.2:

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 **[45 kcal (188 kJ)]** and not more than 70 kcal (293 kJ) of energy.

ISDI does not support having a cut-off point at 24 months of age.

Justification:

ISDI fully supports that, when prepared ready for consumption in accordance with the instructions of the manufacturer, the product shall contain no more than 70 kcal (293 kJ) per 100 mL. As for the minimum level ISDI supports a minimum energy density aligned with the energy content of reduced fat cow's milk (45 kcal/ 100 mL).

The proposed energy range of 45-70 kcal/100 mL is considered appropriate based on ~~both~~ the reference to cow's milk and in making a relevant contribution (approximately 15-22%) to the daily dietary energy intake of young children, when consuming an average of 300 mL, as per WHO (2005) guidelines for milk consumption in 6-24 month children.

The ISDI priority is to address the double burden of malnutrition. Prevalence of both undernutrition and overweight is observed in the same community, nation or region. Codex standards should provide flexibility for the requirements for the essential composition of Follow-up Formula for young children (and energy density) in order to address the needs of young children globally. A Codex standard designed

for nutritional products for young children, should be designed to meet the nutritional needs of young children globally.

ISDI does not support having a cut-off point for energy at 24 months as a minimum of 45 kcal / 100 mL can be considered an appropriate energy density for young children when providing adequate levels of both macronutrients and micronutrients.

References

WHO (2005) Guiding Principles for feeding of non-breastfed children 6-24 months of age. World Health Organization: Geneva.

Recommendation 10

Carbohydrates

ISDI supports defining a recommendation for maximum carbohydrate levels of 14 g/100 kcal but seeks clarification from the eWG on the differentiation between total carbohydrates and available carbohydrates.

Minimum Protein

ISDI reiterates its position in CP2 and continues to advocate for a minimum protein level of 1.5 g/100 kcal. ISDI disagrees with the Chair's recommendation for no minimum protein level, or the suggested default minimum of 1.8 g/100 kcal.

ISDI considers it important that minimum protein levels need to be established in the Standard. Protein is essential for growth & development, and Follow-up Formula is expected to be a source of high quality protein in young children's diet. A product without adequate protein levels and quality could negatively impact the ability to meet protein requirements, and may therefore impact growth & development.

Maximum Protein

ISDI disagrees with the Chair's recommendation that no protein maximum limit should be established within the Standard, and continues to support a maximum of 5.5 g/100 kcal.

Total fats

ISDI continues to maintain its previous position of minimum fat levels at 3.5 g/100 kcal. This value may be guided by reduced fat milk (1.5-2% fat, calculated by eWG as 3.5 g/100 kcal). This will enable formulations targeting the lower level of the energy range to be produced.

Justification:

Carbohydrates

Predominantly, carbohydrates in Follow-up Formula for young children include lactose from milk, plus other carbohydrates and sugars. Carbohydrates are an important energy source for the body and are a necessary part of the diet. Therefore, ISDI supports establishing a maximum level for carbohydrates which needs to be balanced with protein and fat levels in order to meet high nutritional quality products. However, at this stage, ISDI could support a maximum level of 14 g/100 kcal**.** Additionally ISDI notes that a maximum of 14 g/100 kcal which equates to 54% of energy is within with the US AMDR for total carbohydrates of 45-65%.

Regulatory provisions for compositional requirements for infant and young child nutritional products generally define levels for either total carbohydrates or carbohydrates.

Therefore ISDI recommends setting compositional requirements for total carbohydrates, particularly as total carbohydrate levels can be easily analyzed contrary to available carbohydrates whose analysis is not straightforward. However, ISDI recognizes that some labelling requirements are also referring to available carbohydrates. Therefore ISDI is requesting the eWG and CCNFSDU to reflect on the provisions for carbohydrates, particularly on the differentiation between total carbohydrates and available carbohydrates.

ISDI supports establishing a maximum for carbohydrates at 14 g/100 kcal, however, it should be noted that this should not be defined in isolation to recommendation 14.

Minimum protein

The minimum protein level suggested by ISDI at 1.5g/100kcal, in addition to being an approximate extrapolation of the lower limit of the US AMDR for a young children total daily protein intake to the individual product, targets ~20% of the DIRV for protein when an average daily serve of 300mL is

consumed. While derived from a different approach, this is similar to some of the minimum levels targeted for other select vitamins & minerals. This minimum will enable a greater flexibility for manufacturers to formulate within the bounds of the proposed energy limits.

* 300mL daily consumption of a formula with 45kcal/100mL and 1.5g protein/100kcal formula would deliver 18% of minimum protein needs (DIRV for protein @ 11.3g/day); a 60kcal/100mL formula 23% and at 70kcal/100mL formula 28% of the DIRV for protein.

Maximum protein

ISDI notes that maximum levels of protein are self-limiting based on the proposed energy maximum of 70kcal/100mL, and proposed maximum carbohydrate limits. However, ISDI consider the status quo of a protein maximum of 5.5g/100kcal should be retained within the Standard. Cow's milk is generally considered as a reference beverage for the category and consumption is recommended in many country dietary guidelines (FAO 2013); the protein level of 5.5 g/100 kcal thus encompasses the ~average protein density of whole cow's milk, a key ingredient in such products.

Further detailed rationale in support of this protein limit is outlined in the ISDI July eWG comments, including consideration of the globally diverse protein intakes/ quality of this age group, where population intake distribution must be accounted for, as well as the lack of UL and absence of any safety concerns with products based on cow's milk with such protein levels, including that many children will continue to benefit from products with a higher proportion of energy from protein, particularly high quality protein.

In summary, the suggested protein limits both minimum and maximum as defined by ISDI enable a broad range of innovations and formulations to market in order to target the global and diverse needs of young children and role of product in diet.

Minimum total fat

ISDI does not support the Chair's proposed minimum fat level of 4 g/100 kcal and continues to advocate for a minimum fat level of 3.5 g/100 kcal. This level is aligned with the upper levels of reduced fat milk.

We note younger children are recommended to consume lower fat levels than infants. FAO recommends a gradual reduction in the energy contribution from fat from 40-60% of energy to approximately 30-35% of energy between 6-24 months (FAO, 2010). Thus it is appropriate that the minimum should not be lower than reduced fat milk in order to cover the broad age range.

References

FAO (2010) Fats and fatty acids in human nutrition: Report of an expert consultation. Food and Nutrition Paper 91.

FAO (2013) Milk and dairy products in human nutrition. Food and Agriculture Organization of the United Nations, Rome.

Alexy U, Kersting M. Time trends in consumption of dairy foods in German children and adolescents. Eur J Clin Nutr 2003; 57:1331-1337

WHO (2005) Guiding Principles for feeding of non-breastfed children 6-24 months of age. World Health Organization.

Recommendation 11

ISDI agrees it is important to define minimum protein quality requirements within the Standard, however does not agree with the Chair's recommendation for protein quality.

ISDI recommends that the requirement for minimum protein quality within the 12-36 month compositional requirements should instead read as follows (including footnotes and Annex I);

[Protein **quality]**

[For an equal energy value the formula must contain an available[1] quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein as outlined in Annex II][2]

[1] Available amino acids determined by ileal amino acid digestibility as recommended by FAO 2013 where data is available, or alternatively, true faecal crude protein digestibility where it is not.

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

Annex I

Essential and Semi-Essential Amino Acids required for 6-36 month children in the Reference Protein[1]

For the purpose of this Standard the essential and semi-essential amino acids required for a 6 – 36 month child from WHO/FAO 2007, and recommended by FAO 2013, expressed as amino acid requirement per gram of protein, are listed.

The level of an amino acid (mg/g protein) is used to calculate the minimum amino acid content per 100kcal of a Follow-up Formula for young children with the minimum protein content of [1.5g/100kcal], accepted in this Standard i.e. mg amino acid/g crude protein multiplied by the minimum total protein defined in the Standard.

	mg/g protein[1]	**mg/100kcal**
		[1.5g/100kcal min[1]]
Histidine	**20**	**30**
Isoleucine	**32**	**48**
Leucine	**66**	**99**
Lysine	**57**	**86**
Phenylalanine + Tyrosine (AAA)	**52**	**78**
Methionine + Cysteine (SAA)	**27**	**41**
Threonine	**31**	**47**
Tryptophan	**8.5**	**13**
Valine	**43**	**65**

[1] Adapted from FAO 2013

Justification:

ISDI recommends the use of an age appropriate amino acid reference pattern that represents the requirements of young children, as defined by FAO (2013), to define protein quality within the Standard for Follow-up Formula for young children.

To ensure the Follow-up Formula for young children meets the appropriate level of amino acids, it is important to adjust the dietary protein for the availability of its amino acids, which defines the digestibility, the chemical integrity and the lack of metabolic interference to ensure the Follow-up Formula for young children delivers the appropriate level of amino acids to the infant. The preferred methodology to measure available amino acids is the ileal digestibility amino acid method as recommended by the FAO 2013. Where ileal digestibility data is not published, values for available amino acids from the protein source should be calculated using faecal crude protein digestibility values, as recommended by FAO 2013, and applied to the Follow-up Formula for young children minimum amino acid content. Therefore the calculation for available amino acids in the protein source is as follows;

Available amino acids = mg amino acid in protein X digestibility factor for the same amino acid

The FAO Expert Consultation compiled the available ileal digestibility data (Moughan et al, 2012) for a range of common foods and food ingredients common within formula, including, skim and whole milk powder, casein/caseinates, milk protein concentrates/isolates, whey protein concentrate, whey powder,

[1] The ISDI recommended minimum total protein content of [1.5g/100kcal] has been used below for comparison purposes).

goat (formula), soy protein concentrate/isolate and other ingredients like casein hydrolysate, pea protein concentrate and rice protein concentrate.

As the FAO (2013) amino acid reference scoring pattern is given as mg available amino acid per gram protein requirement, and Follow-up formula for young children protein content is defined per 100 kcal, further calculation of minimum amino acids per 100kcal are required. The calculation is developed for the minimum protein level (e.g. 1.5g/100kcal) to set a minimum level of amino acids required for a 100 kcal energy unit. For example, the FAO (2013) amino acid reference pattern for young children defines that 20 mg histidine/g protein. If the minimum protein level in a Follow-up Formula for young children is set, for example at the ISDI recommended 1.5 g/100 kcal then the minimum histidine level/100kcal to apply will be;

*20mg histidine/g protein x *[1.5] g protein/ 100kcal [minimum protein in Std]= 30mg histidine*

This is similar to the calculation of the amino acid energy content in Annex I of the Infant Formula Standard & draft Follow-up Formula Standard in which case breastmilk protein is used as the reference protein. For protein ingredients that have a protein quality score of <1 (for example soy protein isolate has score of 0.9 as outlined in Rutherfurd et al, 2015), a slightly higher minimum protein level of 1.67g/100kcal (*ISDI's proposed minimum protein of 1.5g/100kcal divided by the protein quality score*) would be required to meet the minimum amino acid levels. Or alternatively protein quality may be improved by addition of individual amino acids. ISDI recommends that the standard allows for use of either of these options or a combination of both.

Furthermore, ISDI also recommends that the Standard allows addition of individual amino acids to improve protein quality where appropriate (equivalent to footnote 4 in 3.1.3 Section A of the Follow-Up Formula for Older Infants draft Standard)

ISDI notes that the Chair has suggested defining protein quality as >85% of casein. However, without stipulation of a method, it is likely protein quality would still then defer to PER which is not appropriate[11]. The Protein Efficiency Ratio (PER) has previously been used to determine protein quality, but this is an old method and has not been considered gold standard for over 40 years. The PDCAAS method on the other hand is still widely used. Thus ISDI recommends a more appropriate reference pattern that represents the requirements of the young child, such as the 6-36month reference pattern as recommended by FAO 2013 is considered.

References

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Recommendation 12

Although ISDI previously supported a minimum level of α-linolenic acid at 44 mg/100 kcal, ISDI is able to support the proposal of the eWG Chair at 50 mg/100 kcal.

Based on further considerations, ISDI now also supports a minimum level linoleic acid at 300 mg/100 kcal. This is aligned with support from the eWG members, and the ENA expert recommendation to set a minimum level for linoleic acid.

[11] Protein Efficiency Ratio (PER) is a well-known method to assess protein quality by means of an animal (rat) growth model, feeding a known quantity of protein to infant animals over the course of 28 days. The score is a ratio of the weight gained relative to the protein consumed. It is typically adjusted for a controlled protein, the animal nutrition research council (ANRC) Casein, which is a hydrochloric acid casein. However, the PER is an old method and has not been considered gold standard for over 40 years. Most recent recommendations promote the use of a (chemical) amino acid scoring method, typically with correction for the bioavailability of the protein with measurement of the digestibility of the protein or amino acids.

Justification:

A-linolenic acid (ALA)

ISDI supports establishing a minimum for **α-linolenic acid** based on inadequate dietary intake of α-linolenic acid in young children globally and can align with the level proposed by the eWG Chair of 50 mg/100 kcal.

Linoleic acid (LA)

ISDI has also been reflecting on **linoleic acid** and notes: this is also an essential fatty acid; there are indications that the dietary intake of LA in young children may be less than the Adequate Intake in a few countries; and the ENA expert panel recommended mandatory LA level. ISDI considers that Follow-up Formula for Young Children could support meeting the linoleic acid dietary requirements for young children and can therefore support a minimum level of 300mg/100kcal, as a default in line with the existing Follow-up Standard. Lastly, no maximum or GUL, nor ratio between both linoleic acid and α-linolenic acid is necessary as there is insufficient evidence to define an optimal ALA;LA ratio if overall intakes are sufficient, as outlined by FAO (2010).

Fat is an important energy source for man, it facilitates the absorption of fat-soluble dietary components such as vitamins and supplies essential fatty acids (α-linolenic acid (ALA) and linoleic acid (LA)) to the body. Dietary intake levels for LA and ALA have been based on expert recommendations defined for n-3 and n-6 fatty acids and have been established at approximately 3-4.5% of energy for LA and [0.4-0.6%] of energy for ALA (AFSSA 2010, FAO 2010, IOM, Uauy, R. and Dangour, A. D., 2009).

Several eWG members recommended a minimum LA level. Similarly an expert opinion coordinated by the Early Nutrition Academy supported a mandatory minimum level of LA when considering the nutritional composition of a Follow-up Formula specifically designed for young children (1-3 years of age) (Suthutvoravut, 2015).

ISDI conducted a more in depth assessment of LA dietary intake data, which revealed that there is limited data available on LA intakes in young children globally. While dietary intake of LA can be considered sufficient in some countries (EFSA, Michaelsen, 2011), there is indication that in other countries LA intakes are inadequate:

- EFSA concluded that overall dietary intake of LA in young children in Europe do not give rise to concern (EFSA 2013)
- In France, however, a study showed that 51% of young children (1 – 2 years) consuming cow's milk were found to have inadequate dietary LA intake as compared to only 4% for young children consuming a growing up milk fortified with LA (Ghisolfi, 2011);
- In North America, and more specifically in Canada, it was reported that young children generally had dietary LA intake below the Adequate Intake for LA (Health Canada, 2012);
- In selected Asian countries, such as in Bangladesh, Vietnam or China, dietary intakes of n-6 fatty acids are reported below the FAO Adequate Intake (Michaelsen, 2011; Huffman, 2011).

Based on the above evidence, ISDI considers that Follow-up Formula for Young Children should facilitate meeting the dietary requirements of young children for this essential fatty acid and therefore ISDI would like to maintain the minimum of 300mg/100kcal.

In conclusion, ISDI supports the eWG Chair's recommendation to propose a minimum ALA requirement at 50 mg/100 kcal. ISDI also recommends further consideration is given to the appropriateness of including a minimum for LA and can support maintaining the minimum LA requirement of 300 mg/100 kcal.

References

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Michaelsen KF, Dewey KG , Perez-Exposito AB, *et al.* (2011) Food sources and intake of n-6 and n-3 fatty acids in low-income countries with emphasis on infants, young children (6–24 months), and pregnant and lactating women. *Maternal and Child Nutrition,* 7:124–140.

Suthutvoravut U, Abiodun PO, 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*, 67:119-32.

Uauy, R. and Dangour, A. D. (2009). Fat and fatty acid requirements and recommendations for infants of 0–2 years and children of 2–18 years. *Ann. Nutr. Metab*. 55:76–96.

Recommendation 13

ISDI supports the eWG chair that commercially hydrogenated oils and fats shall not be used in Follow-up Formula for young children.

As per the ISDI position in CP2 and justification given below, if a maximum for TFA were to be set it should enable the levels found in milk and milk fat.

In this case, ISDI will provide further comment.

Justification:

ISDI reiterates the justification given on TFA from its answer to CP2 in July 2016.

Current recommendations by the WHO/FAO from 2008 state trans-fatty acids (TFAs) should be below 1% of total energy intake. The evidence for the association of these fatty acids with major health and disease outcomes was graded as "convincing" by WHO (2010). EFSA established DRVs on all the fatty acids in 2010 as well and their recommendation for TFA intake is to keep 'as low as possible'. The ENA recommends keeping trans-fatty acids below 2% of total fat, because of the potential adverse effects. Nevertheless, regulators, public health bodies and WHO/ FAO are still working to reduce the detrimental effects of TFA in the diet by trying to limit/ban industrial TFA, but not intakes of ruminant TFA which are naturally inherent in the milk (EC, 2015; FAO,2010; UAUY, 2009).

Inclusion of a clause banning the use of hydrogenated vegetable oils in Follow-up Formula for young children could effectively eliminate industrial TFA from these products. Industrial and ruminant TFA contain some similar compounds, yet in different proportions. In 2010, the European Food Safety Authority outlined that the available evidence indicated that TFA from ruminant sources could have adverse effects on blood lipids and lipoproteins similar to those from industrial sources when consumed in equal amounts. However, at the same time, there is insufficient evidence to establish whether there is any difference between ruminant and industrial TFA consumed in equivalent amounts on the risk of heart disease (EFSA, 2010).

More recently, a systematic review and meta-analysis commissioned by the World Health Organisation (de Souza et al., 2015) reported that industrial, but not ruminant, trans fats were associated with coronary heart disease (CHD) mortality (1.18 (1.04-1.33) vs 1.01 (0.71-1.43 for ruminant)), and CHD (1.42 (1.05-1.92) vs 0.93 (0.73-1.18)). Ruminant trans-palmitoleic acid was associated positively (protective) with type-2 diabetes (0.58 (0.46-0.74)).

In 2013, FAO acknowledged that the quantity of TFA consumed may also be a factor in the disease risk. Present knowledge on TFA intakes in most countries is not robust (FAO 2013).

The quantities of ruminant TFA (rTFA) consumed are low in most of the populations studied (generally <1.0 percent E). Thus, even when total ruminant fat intake is relatively high, the potential amount of TFA from this source is still quite modest. These data do not discount the possibility that much higher amounts of ruminant fat could have adverse effects, but in the amounts consumed in actual diets rTFA do not appear to be major contributors to CHD risk (FAO 2013).

FAO (2013) also noted that, at amounts currently consumed, rTFA do not have detectable adverse relationships with disease risk but further investigation is warranted. At the present time, both sources of TFAs, and especially specific TFA isomers, should be considered when assessing effects on disease risk (Mozaffarian, Aro and Willett, 2009, cited in FAO 2013).

Regarding the inherent levels of ruminant TFA in milk: the eWG summarised data that suggested whole milk and skim milk TFA levels range from 0.1- 6.5% TFA in the milkfat. However, data averages from analysis of milkfat and whole milk do not support this low minimum value. Milk data from over 14

European countries shows average TFA levels as a proportion of total fat in milk are significantly higher ranging from 3.19-5.09% (Aro, 1998), with data from British supermarkets also showing average levels of 3.78-5.46% (Kliem et al, 2013). Analysis of milkfat by Precht and Molkentin (2000) also supported average data from some countries around 4-5.5%.

References

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Lindmark-Mansson et al (2003) Composition of Swedish dairy milk. International Dairy Journal 13 409-425.

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O'Donnell-Megaro (2013) Survey of the fatty acid composition of retail milk in the United States including regional and seasonal variations. J. Dairy Sci. 94 :59-65.

Precht D, Molkentin J (2000) Trans unsaturated fatty acids in bovine milk fat and dairy products. Eur. J. Lipid Sci. Technol. 102, 635-639.

Rego et al (2016) Changes in milk production and milk fatty acid composition of cows switched from pasture to a total mixed ration diet and back to pasture. Italian Journal of Animal Science 1591) 76-86.

Uauy et al (2009) Review: WHO Scientific Update on trans fatty acids: summary and conclusions. EJCN 63, 568-75.

Recommendation 14

ISDI would like to reiterate that recommendation 10 should not be made in isolation of recommendation 14 and would advise that these two recommendations become one to ensure full clarity.

Lactose

ISDI agrees with the eWG Chair proposal that lactose should be the preferred source of carbohydrate.

In addition, ISDI recommends the exclusion from from this provision of low lactose products and those based on vegetable protein and would like to introduce a specific footnote that reads as follows:

x) **In order to cope with lactose intolerance, low lactose products as well as products based on vegetable protein are excluded.**

Sugars other than Lactose

In its commitment to reduce intake of free sugars globally, ISDI proposes new wording: '*Added sugars (mono- and disaccharides) which include sucrose and/or fructose, other than lactose, should not exceed 10% of total energy*]'.

Other carbohydrates:

ISDI does not support the inclusion of a list of preferred carbohydrate sources.

Justification:

ISDI supports the ENA 2015 recommendation regarding permitted carbohydrates: Oligosaccharides, glucose polymers, maltodextrin and pre-cooked or gelatinised starches can be added to provide energy. Non-digestible carbohydrates and fibres that proven to be safe and suitable for the age group may be added.

However, ISDI does not consider defining a positive prescriptive list of permitted carbohydrate sources is necessary.

Recommendation 15

IRON

Minimum ISDI supports the eWG recommendation (1.0 mg/100 kcal)

GUL: ISDI supports a GUL of 3.0 mg/100 kcal (rather than a Max of 3.0 mg/100 kcal)

IRON - PRODUCT BASED ON SOY PROTEIN ISOLATE

Minimum: ISDI supports the eWG recommendation (1.5 mg/100 kcal).

GUL: ISDI supports a GUL of 3.5 mg/100 kcal.

VITAMIN C

MINIMUM: ISDI supports a minimum of 4.5 mg/100 kcal.

GUL: ISDI supports the eWG recommendation for a GUL of 70 mg/100 kcal.

Justification:

IRON

Minimum & GUL

ISDI supports the eWG recommendation for a minimum of 1.0 mg/100 kcal

The option for a GUL of 3.0mg/100kcal, as opposed to a maximum level, is supported by ENA, which proposed compositional requirements for Follow-up Formula for young children based on nutritional requirements and safety (Suthutvoravut et al., 2015).

References

Suthutvoravut U, Abiodun PO, 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, 67:119-32.

IRON - PRODUCT BASED ON SOY PROTEIN ISOLATE

Minimum & GUL

For [name of product] based on soy protein isolate, ISDI supports the adoption of an approach similar to that for Follow-up Formula for older infants, i.e. the minimum and maximum levels are 0.5 mg/100 kcal higher than the values for milk based formulas to compensate for a potential lower absorption efficiency of iron. As the levels supported for cow's milk based formulas are a minimum of 1.0 mg/100 kcal and a GUL of 3.0 mg/100 kcal, this would correspond to a :

- Minimum of 1.5 mg/100 kcal
- GUL of 3.5 mg/100 kcal

VITAMIN C

Minimum & GUL

ISDI supports the mandatory addition of vitamin C to Follow-up Formula for young children mainly due to its role in aiding iron absorption. A minimum level of 4.5 mg/100 kcal as suggested by ENA (Suthutvoravut et al., 2015), and which corresponds to 20-30% of the FAO/WHO NRV (at 45-70 kcal/100 mL & a 300 mL serving) seems to be appropriate.

As outlined in its response to CP2, ISDI supports a GUL of 70 mg/100 kcal. This is in line with the eWG recommendation.

Vitamin C is one of the most challenging nutrients for the young child formula manufacturers due to a multitude of factors including its stability, analytical variability, etc. Vitamin C degrades rapidly in water when exposed to air. Loss over shelf life is considerably greater in liquids than in powders and depends on product form and package type. Powder products are generally packed under nitrogen and the available oxygen that remains in the powder after packaging quickly drops during the first week (to almost zero). Liquid products generally do not have this stability after the first week and, depending on package and shelf life, losses are typically 30–50% but may be as high as 75% (MacLean et al., 2010). It is important that the range for vitamin C takes into account factors relating to the product, shelf-life and packaging to ensure that young children (12-36 months) receive the recommended intake. ISDI supports a GUL of 70 mg/100 kcal as defined in the standard for Follow-up Formula for older infants.

References

MacLean WC, Van Dael P, Clemens R, Davies, J, Underwood E, O'Risky L, Rooney, D; Schrijver J. (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

Suthutvoravut U, Abiodun P, Chomtho S, Chongviriyaphan N, Cruchet S, Davies P, Fuchs G, Gopalan S, van Goudoever J, delaReyNel E 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. Ann Nutr Metab, 67:119-132.

Recommendation 16

CALCIUM

Minimum: ISDI supports the eWG recommendation of 90 mg/100 kcal.

GUL: On account of technological issues, ISDI would welcome a review of this GUL once the protein levels have been finalised. However, ISDI could tentatively support the proposal of the eWG.

RIBOFLAVIN

Minimum ISDI favours a minimum of 70 µg/100 kcal however is also able to compromise with the eWG recommendation on 80 µg/100 kcal.

GUL: ISDI proposes a GUL appropriate for Follow-up Formula for young children at 650 µg/100 kcal instead of 500 µg/100 kcal.

VITAMIN B12

Minimum: ISDI supports a minimum of 0.15 µg/100 kcal

GUL: ISDI can support the eWG recommendation for a GUL of 2.0 µg/100 kcal.

CALCIUM:PHOSPHORUS RATIO

As outlined in its response to CP2, ISDI is considering whether a ratio is necessary.

Justification:

CALCIUM

Minimum

As outlined in its response to CP2, ISDI supports the eWG recommendation for a minimum of 90 mg/100 kcal. This is aligned with the current Standard.

GUL

ISDI supports a GUL for calcium. As noted in the ISDI Report 'Technological aspects relating to the establishment of nutrient ranges in Follow-up Formula for young children (12-36 months)' specific consideration must be given to the interactions between calcium and protein**.** In milk, there is a super saturation of calcium due to the colloidal structure of the casein micelle. The structure highlights/reiterates the strong correlation between protein and calcium levels. On account of this, it is not possible to consider either nutrient in isolation and discussions should focus on the interactions

between both. For this reason, ISDI would welcome a review of this GUL once the protein levels have been finalised. However, ISDI could tentatively support the proposal of the eWG of 280 mg/100 kcal.

RIBOFLAVIN

Minimum

Similar to the approach taken with other nutrients, ISDI propose that 30% of the NRV (0.5mg/day) per 300mL is targeted for minimum levels, resulting in 0.07mg (70 µg /100kcal).

GUL

ISDI does not consider the suggested GUL of 500 µg /100kcal is appropriate for Follow-up Formula for young children and instead proposes 650 µg /100kcal as a more appropriate GUL that reflects inherent levels in core milk ingredients.

Milk levels vary considerably as a result of processing, exposure to light etc., and average levels in milk ingredients are greater than the proposed GUL of 500 µg/100 kcal (at 549 µg /100kcal) as summarised by the Chair from Food Composition tables data. Liquid skim (0.5% fat) milk riboflavin sits at 649 µg /100kcal and powder 663 µg /100kcal (Sivakumaran, 2015).

References

MacLean, W.C; Van Dael. P; Clemens, R; Davies, J; Underwood, E; O'Risky, L; Rooney, D; Schrijver, J. 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

Sivakumaran, Subathira. The Concise New Zealand Food Composition Tables, 11th Edition 2014. S. Sivakumaran, L Huffman, S. Sivakumaran, Palmerston North, New Zealand. The New Zealand Institute for Plant & Food Research Limited and Ministry of Health, 2015

VITAMIN B12

Minimum

ISDI disagrees with the Chair's proposal to lower the vitamin B12 levels to 0.1 µg /100kcal for Follow-up Formula for young children (12-36m) and continues to support a minimum level of 0.15 µg /100kcal.

ISDI notes the rationale for mandating this nutrient is because milk contributes a meaningful amount to the young child's diet, however minimum levels of B12 in whole milk is higher at 0.4 µg /100kcal, with average levels at 0.82 µg /100kcal (FAO, 2013).

Thus, ISDI continue to advocate that minimum B12 levels are at least 0.15 µg /100kcal which delivers approximately 30% of the DIRV per 300mL serve at 70kcal/100mL.

GUL

ISDI can support the proposed GUL of 2.0 µg /100kcal. However, ISDI notes as a general principle when setting upper limits for nutrients within the Standard for Follow-up Formula for young children where core milk ingredients are a significant contributor, it is not appropriate to use average milk levels to guide this, instead upper levels or mean +/-3SD should be used in order to reflect the variability in core ingredients used in such formulations.

Reference

FAO (2013) Milk and dairy products in human nutrition. Food and Agriculture Organization of the United Nations, Rome.

Recommendation 16

Mandatory: ISDI maintains its position that zinc should be included as a mandatory (core) nutrient in Follow-up Formula for young children (12-36 months).

Minimum: ISDI favours the mandatory addition of zinc at a minimum level of 0.6 mg/100kcal but can support the eWG recommendation of 0.5 mg/100 kcal in the spirit of compromise.

GUL: ISDI proposes a GUL of 2.1 mg/100 kcal.

Justification:

Mandatory nutrient

ISDI supports the mandatory addition of zinc to Follow-up Formula for young children. The Nutrition Association of Thailand and the Early Nutrition Academy has identified zinc deficiency as a public health concern and has noted that It is of particular concern in developing countries, where plant based diets

predominant. For this reason it meets one of the key principles (section 4.2 CX/NFSDU 16/38/6) developed to help guide and justify mandatory (core) composition (contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale).

Minimum:

As outlined in the CP2 response of July 2016, ISDI supports the mandatory addition of zinc at a minimum level of 0.6 mg/100 kcal. If 30% of the NRV is targeted (approx. 0.41 mg/100 mL), this is equivalent to 0.6-0.91 mg/100 kcal at 70 and 45kcal/respectively. However, ISDI can support the eWG proposal for the minimum to be established at 0.5 mg/100 kcal.

GUL:

ISDI previously supported the GUL for zinc of 1.8 mg/100 kcal. Since then, ISDI identified a large randomized trial among young children using fortified milk with zinc at 2.1 mg/100 kcal, where this product reduced respiratory and diarrheal morbidity (Sazawal et al, 2007). Therefore, ISDI supports to establish the GUL for zinc at 2.1 mg/100 kcal.

References

Sazawal, S., U. Dhingra, P. Dhingra, G. Hiremath, J. Kumar, A. Sarkar, V. P. Menon and R. E. Black. (2007) Effects of Fortified Milk on Morbidity in Young Children in North India: Community Based, Randomised, Double Masked Placebo Controlled Trial. Bmj 334, no. 7585: 140.

Suthutvoravut U, Abiodun PO, 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, 67:119-32.

Recommendation 17

MANDATORY: ISDI supports the mandatory addition of Vitamin A to Follow-up formula for young children.

Minimum: ISDI supports the eWG recommendation for a minimum of 60 µg RE/100 kcal.

Maximum: ISDI supports a maximum of 225 µg/100 kcal.

Footnote:

Regarding footnote 10 that states “any carotenoids should not be included in the calculation and declaration of vitamin A activity”, ISDI notes further consideration is required by the eWG.

Justification:

Mandatory:

ISDI supports the mandatory addition of vitamin A to Follow-up Formula for young children. The Nutrition Association of Thailand and the Early Nutrition Academy has identified vitamin A deficiency as a public health concern. For this reason it meets one of the key principles (section 4.2 CX/NFSDU 16/38/6) developed to help guide and justify mandatory (core) composition (contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale).

Minimum:

As outlined in the CP2 response, ISDI supports the mandatory addition of vitamin A to Follow-up Formula for young children at a minimum level of 60 µg RE/100 kcal. This is in line with the eWG recommendation.

Maximum:

As outlined in the CP2 response, ISDI considers a maximum of 225 µg/100kcal is acceptable for Follow-up Formula for young children on the basis of:

- A maximum is more appropriate than a GUL due to the potential toxicity of vitamin A.
- The IOM provides an upper limit of 600 µg/day vitamin A for children aged 1-3 years old. Targeting 50% of the UL vitamin A = 300 µg/day. If this is provided in 300mL/ day and at an energy range of 45-70kcal/100mL, the child could receive between 142.9 – 222.2 µg Vitamin A per day.
- Further support for this level is provided when taking the approach to multiply the Follow-up Formula for Young Children minimum level of vitamin A (0.6 µg/100kcal) by 3-5 times, providing 180 – 300 µg/100kcal. The level of 225 µg/100kcal is within this range.

- The current Codex Standard for Follow-up Formula provides a maximum vitamin A level of 225 µg (RE) /100kcal and this is similar to the maximum of 200 µg/100kcal recommended by ISDI for Follow-up Formula for Older Infants (ISDI 2016)

For these reasons, ISDI supports a vitamin A maximum of 225 µg (RE) /100kcal for Follow-up Formula for young children.

Footnote:

Regarding footnote 10 that states "any carotenoids should not be included in the calculation and declaration of vitamin A activity", ISDI notes further consideration is required by the eWG.

ISDI notes that while there may be uncertainty about the rate of conversion of beta carotene to vitamin A in young infants, it is not disputed that such conversion does, in fact, occur (Haskell MJ., 2012). Moreover, all other foods for young children and older infants, declare the vitamin A content while including the contribution from beta carotene, using established conversion rates (Codex Food Labeling paragraph 3.4.4, footnote 4). There is no reason to think that the conversion rate is different for beta carotene in complementary foods from that in Follow-up Formula. Consequently, CCNFDSU may be inadvertently creating an inconsistency in food labeling by not permitting the declaration of vitamin A on follow up formulas to include that derived from beta carotene.

References

Haskell MJ. (2012) The challenge to reach nutritional adequacy for vitamin A: β-carotene bioavailability and conversion--evidence in humans. Am J Clin Nutr. 96(5):1193S-203S.

Suthutvoravut U, Abiodun PO, 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, 67:119-32.

Recommendation 18

Mandatory: ISDI supports the mandatory addition of vitamin D to Follow-up Formula for young children (12-36 months).

Minimum: ISDI supports the eWG recommendation for a minimum of 1.5 µg /100 kcal.

Maximum: ISDI supports the eWG recommendation for a maximum of 4.5 µg /100 kcal.

Justification:

Mandatory:

ISDI supports the mandatory addition of vitamin D to Follow-up Formula for young children. The International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy has identified vitamin A deficiency as a public health concern. For this reason it meets one of the key principles (section 4.2 CX/NFSDU 16/38/6) developed to help guide and justify mandatory (core) composition (contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale).

Minimum:

As outlined in the CP2 response of July 2016, ISDI supports the mandatory addition of vitamin D to Follow-up Formula for young children at a minimum level of 1.5 µg /100 kcal. This is in line with the eWG recommendation.

Maximum:

As outlined in the CP2 response of July 2016, ISDI supports the mandatory addition of vitamin D to Follow-up Formula for young children at a maximum level of 4.5 µg /100 kcal. This is in line with the eWG recommendation.

Recommendation 19

ISDI supports the eWG recommendation for a maximum sodium level of 85 mg/100 kcal

Justification:

As outlined in the CP2 response of July 2016, ISDI supports that sodium is included on the mandatory list and that the maximum level is established at 85 mg/100 kcal. This is in line with the eWG recommendation.

Recommendation 20

ISDI supports the recommendation to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. Section A will refer to the essential composition and labelling of Follow-up Formula for older infants, and Section B will deal with the essential composition and labelling of Follow-up Formula for young children.

Justification:

ISDI appreciates the considerations of the eWG Chair and supports the recommendation to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. Section A will refer to the essential composition and labelling of Follow-up Formula for older infants, and Section B will deal with the essential composition and labelling of product for young children.

Recommendation 21

ISDI supports the use of distinctly different names for the two product categories. The name selected should be short and reflect the age specificity of the different product categories.

ISDI does not support the eWG recommendation for the suggested alternative names proposed for Follow-up Formula for young children as a name.

Moreover, ISDI suggests to amend the proposed definitions as follows:

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

~~**[Fortified milk product]** OR **[Processed milk product for young children]** OR~~ [Follow-up formula for young children] [means a product ~~intended~~ **specially manufactured** for use as a liquid part of the ~~progressively~~ diversified diet ~~when nutrient intakes may not be adequate to meet~~ **in order to contribute to** the nutritional **needs** of young children]

Justification:

ISDI notes that there is desire for Follow-up Formula for young children to be easily distinguishable from Follow-up Formula for older infants so as to avoid consumer confusion about the suitability of individual products for different age groups. The suggestion is that this could be achieved by using distinctly different names for the different product categories.

ISDI's preference is to have short names that can be adopted by regulatory bodies and easily understood by consumers. Therefore, careful consideration of names is recommended in order to facilitate greater harmonisation and consistency.

ISDI supports the qualification of this type of food as being specially manufactured for older infants and young children in the definition of the product as to avoid any confusion.