COMMENTS FROM AUSTRALIA NEW ZEALAND INFANT NUTRITION COUNCIL ON

Agenda Item 5 **CX/NFSDU16/38/6**

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

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

Summary of Views

INC wishes to present the following comments on the above Agenda Item in order to contribute to the Government positions now being prepared. These comments specifically address several of the recommendations.

Composition 6-12 months

In relation to recommendations for 6-12 months, INC confirms earlier advice supporting:

- Protein minima of 1.65g/100kcal and maxima of 3.5g/100kcal.
- Alignment with Codex Stan 72-1981 and adoption of a nitrogen conversion factor of 5.71 for soy-based formula.
- The inclusion of minimum levels for amino acids in Footnote 3 using the amino acid composition of breast milk as a reference.
- A higher protein minimum for soy-based follow-up formula proposed in footnote 5
- Inclusion of a footnote 6 where non-hydrolysed formula between 1.65 and 1.8g/100kcal and hydrolysed formula less than 2.25g/100kcal are clinically evaluated when needed, possibly with the evaluation of the data by a competent national or regional body.

Composition 12-36 months

In relation to recommendations for 12-36 months, the following updates or confirms earlier advice from INC on selected recommendations. We particularly draw your attention to the following in relation to INC's views:

- Does not support adoption of minimum limits for energy for young children over 12 months and young children over 24 months; rather, supports one energy range for the age group 12-36 months of 45–70kcal
- Strongly agrees that no minimum carbohydrate level is required; supports a maximum for available carbohydrates but does not support a level of 12g/100kcal; a maximum should not exceed 14g/100kcal (2.9mg/100kJ) but if a lower maximum of available carbohydrate is necessary, then this must not be less than 12.5g/100kcal.
- Minimum protein level set at 1.5g/100kcal; maximum is self-limiting based on proposed energy maximum of 70kcal/100mL; no objection to retaining maximum of 5.5g/100kcal.
- Does not support a limit for fat >4g/100kcal and instead supports a minimum level of 3.5g fat/100kcal in line with upper levels of reduced fat milk.
- Agrees it is important to define minimum protein quality requirements but does not agree with the proposal presented; is further considering application of the age appropriate amino acid scoring pattern with adjustment for bioavailability, and will revert with further comments.
- Recommends the Standard allow addition of individual amino acids to improve protein quality where appropriate

- Supports minimum ALA level of 44mg/100kcal, but can support a minimum of 50mg/100kcal.
- Supports TFA proposal which will limit sources of industrial TFA in formulations, without restricting use of skim/whole milk ingredients due to inherent presence of TFA in milkfat.
- Proposes deleting the requirement: "…Only precooked and/or gelatinized starches gluten-free by nature may be added…" because there is no justification for such a requirement.
- Supports restriction of **sugars, other than lactose** to no more than **10% of total energy**
- Supports a mix of carbohydrate sources with lactose stated as the preferred source of carbohydrate but does not agree with prescribing a % minimum of lactose.
- Supports a minimum calcium level of 90mg/100kcal; GUL not necessary but could support GUL of 280mg/100kcal as this is technically feasible.
- Prefers a minimum riboflavin level of 75ug/100kcal but could support 80ug/100kcal; GUL not necessary and does not support proposed GUL of 500ug/100kcal; higher GUL of 650ug/100kcal would better reflect the variable levels present in core milk ingredients.
- Does not support proposal to lower Vitamin B12 levels to 0.1ug/100kcal; continues to support a minimum level of 0.15ug/100kcal; GUL not necessary but can support proposed GUL of 2ug/100kcal as this is technically feasible.
- Supports mandatory addition of zinc; prefers minimum of 0.6mg/100kcal than 0.5mg/100kcal.
- Supports vitamins A and D and zinc being included in the mandatory composition.
- Strongly suggests simplification of the approaches proposed by the eWG for nutrients not mandated for FuF for 12-36 months but included in essential composition for FuF 6-12 months; points out that proposed approaches for upper limits are problematic for phosphorus, potassium, magnesium chloride and possibly for zinc. (INC considers phosphorus is a special case which will need to remain open depending on whether or not a calcium to phosphorus ratio is mandated or not); supports no minimums being applied to non-mandatory nutrients.
- INC supports dividing the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5.
- INC supports use of distinctly different names for the two product categories. For practicality the names selected should be short and reflect the age specificity of the different product categories.

FUF Composition 6-12 months

eWG Recommendations	INC Comments (Justification follows)
Recommendation 1: That CCNFSDU agree to revise the protein requirements as follows: Protein Unit Minimum Maximum GUL g/100 kcal [1.8] [3.0] - g/100 kJ [0.43] [0.72] - 2) For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a	INC remains of the view that it would be appropriate to adopt a lower minimum protein level of 1.65g/100kcal 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. INC also remains of the view that the protein maximum should be 3.5g/100kcal.

different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of [5.71] as a specific factor for conversion of nitrogen to protein in other soy products. 3) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I [of the Codex Standard for Infant Formula (CODEX STAN 72-1981)]); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together. 4) Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used. 5) The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' 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. [6) Follow-up formula based on non-hydrolysed milk protein containing less than [2 g protein/100 kcal] and] follow-up [formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].	INC supports 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. INC agrees that minimum levels for amino acids should be included in Footnote 3 using the amino acid composition of breast milk as a reference and notes the calculation per 100kcal may need to be addressed. INC supports a minimum value of 2.25g/100kcal (0.5g/100kJ) for soy-based follow-up formula. INC supports the inclusion of a modified Footnote 6 and would propose: • Follow-up formula based on non-hydrolysed milk protein containing 1.65-1.8g protein/100kcal should be clinically evaluated when needed [and data reviewed by a competent national and/or regional authority]. • Follow-up formula based on hydrolysed protein containing less than 2.25g protein/100kcal should be clinically evaluated when needed [and data reviewed by a competent national and/or regional authority].

JUSTIFICATION

For adopting a lower minimum protein level of 1.65g/100kcal and a footnote to accompany the protein level, to ensure that low protein levels are scientifically substantiated, and, when needed, clinically evaluated.

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.

In addition, the lower level takes into account that essential amino acids 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 breast milk.

The full justification and references were provided in the INC response to CP1 2016 in April 2016.

INC also remains of the view that the protein maximum should be 3.5g/100kcal.

INC continues to support a maximum protein level of 3.5g/100kcal on the basis that no new scientific evidence regarding protein requirements and upper safe protein intake levels has become available since the 37th session of CCNFSDU. We refer to previously submitted comments in support of the scientific and general substantiation of a maximum protein level of 3.5g/100kcal.

INC supports 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.

INC notes that CNFSDU37 agreed to request CCMAS to provide advice on the accuracy and appropriateness of 5.71 as the nitrogen factor for soy protein. The discussion was subsequently referred to the CAC; however, discussions were postponed due to resource constraints and other priorities. It was agreed that it would be given consideration at a later stage with a more defined scope.

INC agrees that minimum levels for amino acids should be included in Footnote 3 using the amino acid composition of breast milk as a reference.

However since the publication of the Codex Standard for Infant Formula and its Annex I, new publications have described the amino acid profile in human milk including recent systematic reviews (Zhang 2013, Lönnerdal 2016) and should be considered.

In addition, Annex I of the Codex Standard for Infant Formula describes the levels of essential and semi-essential amino acids expressed per g of nitrogen, per g of protein and per 100kcal. The average level of an amino acid (mg per g of nitrogen) from each study described and used to calculate the corresponding amino acid content per 100 kcal of an infant formula assuming a minimum protein content of 1.8 g/ 100 kcal. If the eWG and Committee supported adoption of a minimum of 1.65g/100kcal for follow-up formula for older infants, new calculations should be made using a factor of 1.65.

INC supports inclusion of a modified Footnote 6 and would propose:

- Follow-up formula based on non-hydrolysed milk protein containing 1.65-1.8g protein/100kcal should be clinically evaluated when needed [and data reviewed by a competent national and/or regional authority].
- Follow-up formula based on hydrolysed protein containing less than 2.25g protein/100kcal should be clinically evaluated when needed [and data reviewed by a competent national and/or regional authority].

INC considers that all formulas containing a protein content between 1.65 and 1.8g/100kcal should be scientifically substantiated, and when needed, clinically evaluated. This will confirm their safety and suitability. Clinical evaluation may not be ethical at a point where there is general agreement that the scientific data is sufficient to prove the safety of all follow-up formulas manufactured from milk protein with a protein content within this range.

INC considers that follow-up formula for older infants containing a protein level between 1.8g and 2.0g/100 kcal do not require clinical evaluation, in agreement with a recent EFSA assessment (EFSA, 2014).

INC 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 during infancy (Berseth, 2009; Vandenplas, 2016).

It is also the case that where hydrolysed protein containing less than 2.25g/100 kcal has been clinically evaluated for use in the more vulnerable infant (0-6 month) population, then further substantiation for use in the older population is not necessary and should not be required.

Therefore INC proposes that footnote 6 should read:

> "Formulas **based on non-hydrolysed milk protein containing 1.65-1.8g protein/100kcal should be clinically evaluated when needed as should formulas** based on hydrolysed protein containing less than 2.25g/100kcal. [Data from such clinical evaluations should be reviewed by a competent national and/or regulatory authority.]"

FUF Composition 12-36 months

eWG Recommendations	INC Comments
Recommendation 8: That CCNFSDU agree to the following revised framework for the essential composition of follow-up formula for young children and identify the preferred option for the optional addition of other nutrients: **Mandatory (core) composition** It is proposed that the mandatory (core) composition of follow-up formula for young children include a limited list of essential nutrients (specific recommendations are presented in Section 5). 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: • as per the min, max, GULs stipulated for follow-up formula for older infants; or • amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants. Note: all footnotes relevant to these listed essential nutrients for older infants, also apply when added to follow-up formula for young children.	Philosophically INC prefers the addition of any optional ingredients to follow a principle-based approach, but recognises that this idealistic approach does not allow a practical solution for the management of non-mandatory nutrients included in the essential composition for Follow-up Formula for Older Infants. INC strongly favours simplification of the proposals put forward to manage these particular nutrients. The approach taken for Follow-up Formula for Older Infants to manage additional ingredients selected from nutrients included in the infant formula standard involves inclusion of a positive list of the selected nutrients with upper limits stated which apply when they are added. This list is non-exhaustive and allows a principle-based approach to be applied for other optional ingredients. This approach is preferred as it provides greater clarity. As a general principle INC recommends no minimum levels are specified for non-mandatory nutrients. In addition, INC has identified issues with the upper limits proposed to be applied for some of these nutrients. These exceptions need to be recognised and managed to achieve an effective and meaningful standard. INC therefore is opposed to the proposal put forward for mandatory (core)

	composition and recommends option 1 proposed for optional additions with modifications that address the issues detailed above. In addition, INC recommends that DHA is listed as an optional ingredient (but without need for corresponding levels of ARA).
Optional Additions	
In addition to the mandatory (core) composition, other nutrients, ingredients or substances may be added to follow-up formula for young children. For the optional addition of other ingredients or substances, it is proposed that a principles based approach will continue. With regards to the optional addition of other *nutrients*, two main options have been identified; (1) optional nutrient additions are chosen from the essential composition of follow-up formula for older infants with corresponding levels as the starting point (Option 1); or (2) optional addition of other nutrients are captured as part of the principles based approach as per the addition of other ingredients and substances (Option 2). Draft text for the two different options and concepts are presented below. The proposed wording represents a starting point for discussion. **OPTION 1:** • In addition to the [essential] compositional requirements listed under [*insert appropriate subsection*] other ingredients or substances may be added to [name of product] for young children where the safety and suitability of the optional ingredient [or substance] for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence. • When any of these ingredients or substances is added, the [name of product for young children] shall contain sufficient amounts to achieve the intended effect, [~~taking into account levels in human milk~~]. • [~~The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are~~	

~~added~~]. *It is proposed to delete the third bullet point in preference for a principles based approach rather than inclusion of any essential nutrients, ingredients or substances in a list.* • [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: - as per the min, max, GULs stipulated for follow-up formula for older infants; or - amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants. Note: all footnotes relevant to these listed essential nutrients for older infants, would also apply when added to [name of product] for young children] **OPTION 2:** • In addition to the [essential] compositional requirements listed under [insert appropriate subsection] other [nutrients,] ingredients or substances may be added to [name of product] for young children where the safety and suitability of the optional [nutrient,] ingredient [or substance] for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence. • When any of these [nutrients,] ingredients or substances is added, the [name of product for young children] shall contain sufficient amounts to achieve the intended effect, [~~taking into account levels in human milk~~]. • [~~The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added~~]. *It is proposed to delete the third bullet point in preference for a principles based approach rather than inclusion of any essential nutrients, ingredients or substances in a list.*	

JUSTIFICATION

INC 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, should be managed by one clause in the optional ingredient section and not by two different clauses as proposed. This would simplify the Standard by eliminating repetition of similar requirements and arguably provide increased clarity.

INC recommends using a similar approach to that taken for Follow-up Formula for Older Infants to manage additional ingredients selected from the infant formula standard in clause 3.3.2.3 in the revised standard. The options for national and/or regional authorities to amend the conditions stated or to include some of these nutrients in the mandatory composition if warranted by the nutritional needs of the local population and scientific justification can be noted.

The eWG proposals 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 do not take into account the 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 to achieve gross composition, may in some cases exceed the permitted levels in Codex Follow-up Formula for Older Infants.

To illustrate this point, the average levels of phosphorus, magnesium and potassium in whole and semi-skimmed cow's milk all exceed the maximum or GUL specified for these nutrients stipulated for follow-up formula for older infants. In addition, the average level of chloride in semi-skimmed cow's milk exceeds the maximum stipulated for follow-up formula for older infants and the upper end of the range of zinc levels in semi-skimmed cows' milk of 0.96mg/100kcal is very close to one of the GUL options under consideration for zinc for follow-up formula for older infants. (Refer to Table 1 of the agenda paper pages 73 and 74). INC considers that any GULs applied to these nutrients for Follow-up Formula for Young Children should accommodate the range of levels naturally found in whole and semi-skimmed cow's milks and similar milks derived from other species commonly used as milk sources, e.g. goat and sheep milks.

Phosphorus needs special consideration and a GUL should be reviewed once the calcium limits are finalised, including a decision on whether or not a calcium to phosphorus ratio is to be specified. Setting a GUL as per that applied for calcium will allow a calcium:phopshorus ratio ≥ 1 to be achieved irrespective of the calcium content. Irrespective of whether zinc is included in the mandatory (core) composition, or included in non-exhaustive list of optional additions, a GUL of 1.0mg/100kcal is not appropriate applying the principle above. It is our recommendation that this is set at 1.8mg/100kcal.

INC is opposed in principle to the specification of minimum levels for non-mandatory nutrients and recommends these are not specified for optional ingredients in alignment with the approach taken in the Infant Formula Standard and for Follow-up Formula for Older Infants in the revised Follow-up Formula standard. Further the minimum levels applied for Follow-up Formulas for Older Infants will not necessarily be appropriate for Follow-on Formula for Young Children as young children consume larger quantities of foods other than Follow-up Formula and these might better be set by competent national or regional bodies as appropriate.

The following possible wording for section 3.3.2 is provided to demonstrate how this section could be presented following INC's suggested approach:

3.3.2 **Optional Ingredients**

3.3.2.1 In addition to the compositional requirements listed under 3.1.2 to 3.1.3, other ingredients or substances may be added to follow-up formula for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

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

3.3.2.3 The following substances may be added in conformity with national legislation, in which

case their content per 100 kcal (100kJ) in Follow-up Formula for young children ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added.

Substances from essential composition of follow-up formula for older infants, 3.1.3 Section A	**Upper limit (Max/GUL) and footnotes**
Vitamin A*	**Max** ug RE/100kcal 200 ug RE/100kJ 48 Footnote 10 as specified for Formula for Older Infants in 3.1.3.
Phosphorus	**GUL** mg/100kcal 280 mg/100kJ 67
Zinc*	**GUL** mg/100kcal 1.8 mg/100kJ 0.43
Other substances	**As specified for follow up formula for older infants in 3.1.3 Section A.**

National and/or regional authorities may deviate from the above conditions, or include some of these nutrients in the mandatory (core) composition, if warranted by the nutritional needs of the local population and scientific justification. Where nutrients from this list are included in the mandatory (core) composition minimum levels applied may need to be set lower than the minimums specified in 3.1.3 to take into account higher intakes from other foods by young children compared to older infants

** If not included in mandatory composition for follow-up formula for young children.*

*** Vitamin A, phosphorus and zinc listed here are examples of nutrients for which INC advocates for upper limits different to those that apply for Follow-up Formula for Older Infants. If this type of approach is adopted all nutrients for which such exceptions apply will need to be stated separately. It is anticipated that this will be a relatively short list, particularly if vitamins A and D and zinc are included in the mandatory composition.*

Docosahexaenoic acid[x]

Unit	**Minimum**	**Maximum**	**GUL**
% of fatty acids	-	-	0.5

[x] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, the content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid.

eWG Recommendations	INC Comments
Recommendation 9: That CCNFSDU agree to the following requirements for energy density: 3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than [60 kcal (250 kJ)] and not more than 70 kcal (293 kJ) of energy. **Additional option for further discussion:** [For products formulated for young children of more than 24 months of age, the product when prepared ready for consumption shall contain per 100 mL not less than 45 kcal (kJ)]	INC does not support the adoption of the proposed minimum limits for energy for young children over 12 months and young children over 24 months. Rather, INC supports one energy range for the age group 12-36 months of 45kcal – 70kcal.
JUSTIFICATION INC supports the adoption of one energy range for the age group 12-36 months of 45kcal – 70kcal. This will accommodate the suggested levels for 12 months+ and for children 24 months+. There is a clear recognition that reduced fat dairy milk products are more suitable for children in the latter age group and current products reflect this.	
eWG Recommendations	**INC Comments**
Recommendation 10: That CCNFSDU agree to include a maximum limit for total carbohydrates as follows: **[Available carbohydrates]** The level of available carbohydrates should not exceed [12 g per 100 kcal (2.9 mg per 100 kJ)] **Additional options for further discussion:** [The level of protein shall not be less than 1.8 g/100 kcal] [The level of total fats shall not be less than 4.0 g/100 kcal]	**Minimum Carbohydrate** INC strongly agrees with the Chairs' conclusion that no minimum carbohydrate level is required within the 12-36month Standard. **Maximum Available Carbohydrate** INC supports the Chair's recommendation that a maximum available carbohydrate should be proposed but does not support a level of 12g/100kcal. INC considers the level of available carbohydrates should not exceed 14g/100 kcal (2.9mg/100kJ). **Minimum Protein** INC considers it important that minimum protein levels are established in the Standard. The minimum protein level suggested by INC at 1.5g/100kcal targets approximately 20% of the DIRV for protein if consumed at 300mL, & while derived from a different approach, this is similar to some of the minimum levels targeted for select vitamins & minerals. **Maximum Protein** INC notes that maximum levels of protein are self-limiting based on the proposed energy maximum of 70kcal/100mL, and

	proposed maximum CHO limit. While INC is sympathetic to the Chair's view not to include a maximum limit for protein, INC does not object to the current status quo for a protein maximum of 5.5g/100kcal is retained. **Minimum Fat** INC does not support the Chair's recommendation that if a limit for fat is to be defined, that this is >4g/100kcal and instead supports a minimum level of 3.5g fat/100kcal in line with upper levels of reduced fat milk.

JUSTIFICATION

Minimum Carbohydrate
As outlined in the July eWG Consultation, **INC considers 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 carbohydrate intakes are not limited in a young child's diet and needs are met by a range of foods in the progressively diversified diet.

INC thus strongly agrees with the Chairs' conclusion that no minimum carbohydrate level is required within the 12-36month Standard.

Maximum Available Carbohydrate
INC proposes the maximum level of available carbohydrates should not exceed 14g/100kcal. INC is open to considering a lower maximum but considers the maximum in the existing standard of 14g/100kcal should be retained until limits are finalized for fat and protein

For example, taking into consideration the INC proposed levels for protein and fat, the capped carbohydrate level of 14g/100kcal meets the Chair's approach to prevent a formula with both low protein (1.5g/100kcal) and low fat (3.5g/100kcal).

Table 1: Residual fat content with set carbohydrate level of 14g/100kcal and varying protein levels

Per 100kcal

Set CHO	**Set Protein**	Fat calculated by difference (approx)
14	1.5	4.2
14	1.6	4.2
14	1.8	4.1
14	3.1	3.5
14	5	2.7 (formulation will not be possible if fat range limited to 3.5-6.0)
14	5.5	2.4 (formulation will not be possible if fat range limited to 3.5-6.0)

Table 2: Residual protein content with set carbohydrate level of 14g/100kcal and varying fat levels

Per 100kcal

Set CHO	**Set Fat**	Protein calculated by difference (approx)

14	3.5	3.1
14	4.2	1.6
14	6	Formulation not possible

INC acknowledges the new approach by the Chair to distribute the macronutrients so products can only be either low fat OR low protein, but not both. INC is generally aligned with this proposal and sympathetic to the Chair's view to cap the carbohydrate level at a level which achieves this. However, the INC considers the proposed level of 12g/100kcal is too low as a maximum and considers the maximum should not be set any lower than 12.5g/100kcal, primarily to provide for the fact that compositions are not precise and vary from typical levels.

Setting a maximum level 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 carbohydrates. 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.

In summary, INC supports the Chair's recommendation that a maximum available carbohydrate that will restrict excess added sugar and refined carbohydrate ingredients to such products. However, INC does not support a level of 12g/100kcal and proposes consideration of a level of available carbohydrates that should not exceed 14g per 100 kcal (2.9mg per 100 kJ) and which takes into consideration the levels of protein and fat that are yet to be agreed.

References

Mozaffarian. (2016) Dietary and policy priorities for cardiovascular disease, diabetes, and obesity. A comprehensive review. *Circulation* 133:187-225.

Maki KC, Phillips AK. (2015) Dietary substitutions for refined carbohydrate that show promise for reducing risk of type 2 diabetes in men and women. *J Nutr.* 2015 Jan;145(1):159S-163S. doi:10.3945/jn.114.195149. Epub 2014 Dec 3.

Minimum Protein

INC notes from Recommendation 11 and the discussion prefixing Recommendation 21, that this, product is intended to be based on cows' milk, milk of another animal or a high quality plant alternative. Since it is theoretically possible to meet the energy requirements without protein, INC considers it important that minimum protein levels are established in the Standard, otherwise products could potentially be formulated without protein.

Protein is essential for growth and 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 and development.

The minimum protein level suggested by INC at 1.5g/100kcal. In addition to being an approximate extrapolation of the lower limit of the US AMDR for a young child's total daily protein intake to the individual product, it targets approximately 20% of the DIRV for protein if consumed at 300mL*. While derived from a different approach, this is similar to some of the minimum levels targeted for select vitamins and minerals. This minimum will enable a broad range of innovations within the Standard, with greater flexibility for manufacturers to formulate within the bounds of the 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
INC notes that maximum levels of protein are self-limiting based on the proposed energy maximum of 70kcal/100mL, and proposed maximum carbohydrate limit. Thus while INC is sympathetic to the Chair's view not to include a maximum limit for protein, INC does not object to retention of the status quo being maximum of 5.5g/100kcal noting this encompasses the ~average protein density of whole cows' milk, and therefore formulations predominately based on cow's milk ingredients with other added core nutrients within scope.

As also outlined in the Chair's comments, it 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 Growing-up Milk formulations through the use of any maximum protein limit that is less than the protein density of whole 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). Further detailed rationale in support of this protein limit is outlined in the INC 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.

In summary, the suggested protein limits (minimum 1.5g/100kcal and maximum 5.5g/100kcal) enable a broad range of innovations and formulations to market in order to target the nutritional needs of young children and the diverse role of the product in diet.

References
Alexy U, Kersting M. (2003) Time trends in consumption of dairy foods in German children and adolescents. *Eur J Clin Nutr* 2003; 57:1331-1337
FAO. (2013) *Milk and dairy products in human nutrition.* FAO, Rome.

Minimum Fat
INC supports the approach to establish minimum levels for fat and protein but not carbohydrate. However, INC does not support the Chair's recommendation that if a limit for fat is to be defined, that this is >4g/100kcal and instead supports a minimum level of 3.5g fat/100kcal.

- A minimum level of 3.5g fat/100kcal is in line with upper levels to those reported for reduced fat milk and thus reflects the broad age range this product is intended to cover, as well as dietary guidelines in those countries where, from 24months, reduced fat milks may be introduced.

- The proposed minimum fat level of 4g/100kcal is limiting for moderate protein formulations, when carbohydrate is also capped. A minimum fat level of 3.5g/100kcal is sought in preference, as this also takes into consideration technical feasibility. Product manufacture is more complex than formulation modelling exercises based on average compositions. In practice manufacturers cannot target minimum or maximum levels, but rather levels within the permitted range that allow enough buffer from minimum and maximum levels to ensure compliance with these. The buffers applied must take account of variability in raw material composition, testing results etc. The eWG was concerned that dietary fat requirements would not be met with 3.5g fat minimum (based on low fat milk), but the minimum ALA level proposed ensures young children meet their essential fatty acid requirements.

eWG Recommendations	INC Comments
Recommendation 11: That CCNFSDU agree to include minimum protein quality requirements as follows: **[Protein]** [The quality of protein shall not be less than 85% of that of casein.]	INC agrees it is important to define minimum protein quality requirements within the Standard, however does not agree with the Chair's proposal for protein quality. INC is further considering application of the age appropriate amino acid scoring pattern with adjustment for bioavailability, and will revert with further comments. INC also recommends that the Standard should allow addition of individual amino acids to improve protein quality where appropriate (equivalent to footnote 4 in 3.1.3 Section A).

JUSTIFICATION

INC agrees it is important to define minimum protein quality requirements within the Standard, however does not agree with the Chair's proposal for protein quality.

INC is further considering the most appropriate approach and text for within the Standard, however at this stage recommends that the requirement for protein quality within the 12-36month compositional requirements could be based upon the FAO (2013) protein quality assessment method which includes the relevant reference amino acid scoring pattern for young children with correction for bioavailability using either ileal amino acid digestibility or, as outlined by the Chair, true fecal digestibility. However, INC will revert with further comments.

Irrespective of the criteria specified for protein quality, there should be an ability to improve protein quality by the addition of individual amino acids where appropriate. INC therefore recommends that there is provision for addition of individual amino acids to improve protein quality as per footnote 4 in 3.1.3 Section A.

<u>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</u>
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 Standard.

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.

References
Rutherfurd SM, Fanning AC, Miller BJ, Moughan PJ. (2015) Protein Digestibility-Corrected Amino Acid Scores and Digestibility Indispensible Amino Acid Scores Differentially Describe Protein Quality in Growing Male Rats. *The Journal of Nutrition*, 145, 372-379.
FAO. (2013) Dietary protein quality evaluation in human nutrition: Report of an FAO Expert Consultation, *FAO Food and Nutrition Paper 92*. FAO, Rome.

eWG Recommendations	INC Comments
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)]	INC's preference as outlined in the earlier submission was for a minimum ALA level of 44mg/100kcal, however INC can support the Chair's proposal for a minimum level of 50mg/100kcal.
eWG Recommendations	**INC Comments**
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].	**TFA** INC are supportive of the Chair's proposal, which is aligned with the recommendation outlined by INC in July 2016. INC considers this clause will effectively limit sources of industrial TFA in such formulations, without then restricting the use of core skim and whole milk ingredients due to the inherent presence of TFA in milkfat.
eWG Recommendations	**INC Comments**
RECOMMENDATION 14: That CCNFSDU agree to the following text on types of carbohydrates suitable for [name of product] for young children: [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]. **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].	INC proposes deleting the requirement: "…Only precooked and/or gelatinized starches gluten-free by nature may be added…" because there is no justification for such a requirement. INC supports restriction of **sugars, other than lactose** to no more than **10% of total energy** INC supports the standard accommodating a mix of carbohydrate sources with lactose stated as the preferred source of carbohydrate. INC does not agree with prescribing a % minimum of lactose.

JUSTIFICATION

INC supports provisions in place to regulate the carbohydrate quality of FUF for young children. INC considers that the key elements that should be included are a statement that lactose should be the preferred carbohydrate and a cap on sugars excluding lactose.

INC does not support specifying an arbitrary minimum lactose content or provision of a positive list of carbohydrates that can be used. There is no such provision in Standard 2.9.3 in the Australia New Zealand Food Standards Code and we are not aware of any issues of concern arising from the absence of such provision. Further, imposing the proposed arbitrary minimum does not accommodate products based on high quality plant proteins which are often no/low lactose products. In this context it is clear that lactose is not the only carbohydrate (other than other sugars with capped content).

INC questions the rationale for including restrictions on starches. We believe these have been inadvertently carried over from the proposals for FUF for older infants. In particular we are opposed to restrictions relating to 'gluten free' for these products and suggest that gluten free products can still be available.

Young children aged 1+ years enjoy a more diversified diet and there is no nutritional reason to restrict gluten or particular starches from 12 months of age. It is noted that Southutvoravut et al (2015) do not advocate for starches added to be gluten free. Further, the proposed statement that 'sucrose and/or fructose should not be added, unless needed as a carbohydrate source' seems to be a carry-over from the proposals for FUF for older infants. INC favours the proposed cap on sugars other than lactose which negates the need for this statement.

In lieu of no other evidence supporting a level of sugars in FUF for young children, INC supports the restriction being modeled on the WHO recommendation for dietary sugar intake. While extrapolation of the WHO (2015) recommendation is not ideal, the approach to restrict sugars to no more than 10% of total energy is more closely aligned than a restriction of less than 10% total carbohydrate.

In summary INC recommends the following text to cover carbohydrate quality:

> "A mix of available carbohydrates may be used but lactose should be the preferred carbohydrate in [name of product], especially for milk-based products. Sugars, other than lactose, should not exceed 10% of total energy."

eWG Recommendations	INC Comments
Recommendation 16: That CCNFSDU agree to the following recommendation for calcium, riboflavin and vitamin B12 levels in [name of product] for young children: **Calcium** Min Max GUL mg/100 kcal [90] -- [280] mg/100 kJ [22] -- [67] **Riboflavin** mg/100 kcal [80] -- [500] mg/100 kJ [19] -- [119] **Vit B12** mg/100 kcal [0.1] -- [2.0]	**Calcium** INC is supportive of the Chair's proposal for a minimum calcium level of 90mg/100kcal. As outlined in the July eWG submission, INC does not consider it necessary to set a GUL for Calcium, however can support the GUL of 280mg/100kcal as this is technically feasible. **Riboflavin** *Minimum* INC has a preference for a minimum riboflavin of 75ug/100kcal but could

mg/100 kJ [0.024] -- [0.48] ***Additional Option for further consideration:*** [Ratio calcium/phosphorous] **Min** **Max** [1:1] [2:1] **Zinc** That CCNFDSU agree that zinc should not be included as a mandatory (core) nutrient for addition to [name of product] for young children. Alternative Option for consideration: If the Committee consider there is sufficient evidence to require the mandatory addition of zinc to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of zinc to [name of product] for young children with the following levels: Zinc Unit Min Max GUL mg /100 kcal [0.5] - [1.8] mg /100 kJ [0.12] - [0.43]	support the Chair's Proposal for a minimum of 80ug/100kcal. INC does not consider it necessary to set a GUL for riboflavin and does not support the proposed GUL of 500ug/100kcal. INC supports a higher GUL of 650ug/100kcal to better reflect the variable levels present in core milk ingredients. **B12** INC disagrees with the Chair's proposal to lower the Vitamin B12 levels to 0.1ug/100kcal within the 12-36month Standard and continues to support a minimum level of 0.15ug/100kcal. While INC does not consider a GUL is necessary, INC can support the proposed GUL of 2ug/100kcal as this is technically feasible. **Zinc** INC supports mandatory addition of zinc. As such INC can accept the alternative option presented but prefers the minimum be set at 0.6mg/100kcal rather than 0.5mg/100kcal.

JUSTIFICATION

Riboflavin

Minimum

INC agrees with the Chair's rationale for inclusion of minimum riboflavin levels within the Standard on the basis that milk is a significant source of this nutrient. INC prefers a minimum riboflavin content of 75ug/100kcal but could support the eWG suggestion of a minimum of 80ug/100kcal, higher than our earlier recommendation of a minimum of 70ug/100kcal.

While these minimum levels are significantly lower than FAO (2013) Food Composition table reported average levels reported in whole milk at 270ug-320ug/100kcal[1], manufacturers will always target levels greater than the minimum in order to assure compliance, particularly in the case of riboflavin which is a light sensitive vitamin that has high losses during processing and over shelf life (for example, degradation can be as high as 60% across shelf life (Maclean et al, 2010).

In a 45kcal/100mL formula, a 300mL serve with 80ug/100kcal will deliver 21.6% of a young child's riboflavin needs, in 60kcal/100mL 29% of the DIRV and at 70kcal/100mL 34% of the DIRV (0.5mg/day).

GUL

INC does not consider the suggested GUL of 500ug/100kcal is technically feasible for FUF for young children which may contain higher protein levels than FUF for older infants and instead

[1] (calculated from FAO, 2013 using an average energy content of 62kcal/100mL)

proposes 650ug/100kcal as a more appropriate GUL that reflects inherent levels in core milk ingredients.

We note it is not nutritionally necessary to establish upper limits for riboflavin within the Standard as: a) there is no UL established for riboflavin and b) there is no evidence of market failure with the current Codex Standard and existing young child formula regulations in ANZ, Indonesia and Malaysia which similarly do not mandate upper limits.

However, if defining a GUL for this nutrient levels in milk may be used as a guide as milk based ingredients are a significant source of riboflavin in GUMs products. Milk levels vary considerably as a result of processing, exposure to light etc, and average levels in reduced fat milk ingredients are greater than the proposed GUL of 500ug/100kcal (at 549ug/100kcal).
as summarised by the Chair from Food Composition tables a Liquid skim (0.5% fat) milk riboflavin sits at 649ug/100kcal and powder 663ug/100kcal (Sivakumaran, 2015). A GUL of 650ug/100kcal, would better enable manufacturers to formulate comfortably within the proposed limits.

References

MacLean WC, Van Dae. P, Clemens R, Davies, 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. (2014). 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.

B12

Minimum

INC disagrees with the Chair's proposal to lower the Vitamin B12 levels to 0.1ug/100kcal within the 12-36month Standard and continues to support a minimum level of 0.15ug/100kcal.

INC 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 0.4ug/100kcal, with average levels of 0.82ug/100Kcal (FAO, 2013).

GUL

INC does not consider a GUL necessary for nutrients which do not have a UL, however can support the proposed GUL of 2.0ug/100kcal. However, INC notes as a general principle when setting upper limits for nutrients within the FUFYC Standard 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.

Zinc

INC supports mandatory addition of zinc. As such INC can accept the alternative option presented but prefers the minimum be set at 0.6mg/100kcal rather than 0.5mg/100kcal.

If 30% of the NRV is targeted (approximately 0.41mg/100ml) this is equivalent to 0.6-0.8mg/100kcal at 70 and 60kcal respectively. We therefore consider that it is inappropriate to set the minimum lower than 0.6mg/100kcal.

eWG Recommendations	INC Comments
Recommendation 17: That CCNFDSU agree that vitamin A should not be included as a mandatory (core) nutrient for addition to [name of product] for young children. Alternative Option: If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin A to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of vitamin A to [name of product] for young children with the following levels and associated footnote: Vitamin A Unit Min Max GUL µg RE10)/100 kcal [60] [180] - µg RE10)/100 kJ [14] [43] -10) 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.	INC supports mandatory addition of vitamin A and therefore the alternative option presented. However, INC seeks for the maximum applied to be set at 200ug RE/100kcal based on the following rationale.

JUSTIFICATION

INC supports mandatory addition of vitamin A and therefore the alternative option presented. However, INC seeks the maximum applied be set at 200ug RE/100kcal based on the following rationale:

The IOM provides an upper limit of 600ugRE/day for children aged from 1-3 years old. Targeting 50% of the UL for vitamin A = 300ugRE/day. If this quantity is to be provided via a 300mL of follow-formula for young children per day then the following vitamin A content is needed:

Energy density	Vitamin A/100kcal
45kcal/100mL	222ugRE
60kcal/100mL	167ugRE
70kcal/100mL	143ugRE

In order to be able to target levels in the range of 143-167ug RE/100kcal the maximum applied needs to take into account the variability in levels from target sought due to

- the variability of vitamin A naturally present in milkfat
- manufacturing and testing variability; and
- the fall-off in vitamin A levels that occurs during product shelf-life.

The maximum proposed of 180ug RE/100kcal does not allow for levels approaching 167ug RE/100kcal to be targeted. Increasing the maximum of 225ugRE/100kcal, as per the maximum that applies in the existing Standard would allow levels in this range to be targeted. The maximum of 200ugRE/100kcal is proposed as a compromise between this concern and concerns raised by some eWG members about potential excessive levels of vitamin A.

eWG Recommendations	INC Comments
Recommendation 18: That CCNFDSU agree that vitamin D should not be included as a mandatory (core) nutrient for addition to [name of product] for young children. Alternative Option: If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin D to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of vitamin D to [name of product] for young children with the following levels: Vitamin D Unit Min Max GUL µg /100 kcal [1.5] [4.5] - µg /100 kJ [0.36] [1.08] -	INC supports mandatory addition of vitamin D as vitamin D deficiency in young children is frequently documented. INC fully supports the alternative option presented where vitamin D addition is mandated within levels specified.
eWG Recommendations	**INC Comments**
Recommendation 20: That CCNFSDU agree 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.	INC supports dividing the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5.

JUSTIFICATION

The product for older infants and product for young children are distinctly different from one another.

This is clearly reflected in the composition with the proposal for product for young children to contain a limited number of mandatory nutrients, compared to follow-up formula for older infants which mandates the addition of 32 nutrients.

INC notes the desire for product for young children to be easily distinguishable from product for older infants so as to avoid confusion about the suitability of individual products for different age groups. INC agrees that two separate parts to the Standard would allow for different composition and labelling approaches to the two different product categories, and this would possibly assist in being able to easily distinguish the different products and consequent roles in the diet from one another.

INC is strongly of the view that the role of product for young children is NOT as a substitute for breast milk, but as a substitute for cows' milk (or milks of other species commonly consumed e.g. goats' milk) . It is 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.

eWG Recommendations	INC Comments
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.]*	INC supports use of distinctly different names for the two product categories. For practicality the names selected should be short and reflect the age specificity of the different product categories. INC does not support the alternative names proposed for Follow-up Formula for Young Children preferring 'Toddler Milk [Drink or Supplement],' or 'Growing-up Milk [Drink or Supplement].' Use of a distinctly different name like this for young child formulas would allow the name used for Follow-up Formula for Older Infants to be abridged to' Follow-Up Formula' for labelling purposes (or 'Follow-on formula' if follow-up formula sought to be retained to cover both products covered in this standard.

JUSTIFICATION

INC 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.

The challenge is to find suitable terms that reflects age specificity that accurately describes the function of the product. It is also important that the name is short in order to be practical as a product name for labelling purposes.

INC does not support the names suggested. The term 'fortified milk for young children' is incorrect. These products will not be milk ingredients plus vitamins and minerals as is the case for fortified milks. For example, vegetable oil(s) will need to be added to deliver the minimum alpha-linoleic acid requirement proposed. The name 'processed milk for young children' is similarly misleading as it ignores the fact that all milks (other than raw milk) are processed to some degree. .

Follow-up formula for young children, as a supplement to the diet substituting milk suggests a term such as 'Young Child Milk Supplement' or 'Young Child Milk Drink' may be appropriate. 'Toddler milk' has recognition in some countries as does 'Growing up milk.' These names or 'Toddler Milk Supplement', 'Toddler Milk Drink', 'Growing-up Milk Supplement' or 'Growing -up Milk Drink' could be considered.

Use of a distinctly different name like this for young child formulas would also allow the name used for Follow-up Formula for Older Infants to be abridged to' Follow-Up Formula' for labelling purposes (or 'Follow-on formula' if follow-up formula sought to be retained to cover both products covered in this Standard).