INC comments on Agenda Item 4

REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987)
(Prepared by the electronic working group led by New Zealand, France and Indonesia)

INC Overarching Comments
INC congratulates the eWG on the progress made this year in preparation for CCNFSDU39.

INC considers that it is very important that the revised standard provides clarity that [name of product] for young children are not formulated nor intended to be substitutes for human milk and this is reflected in our responses to some of the recommendations.

INC notes that the term 'breastmilk substitute' has been omitted from all text proposed. INC can support this given that there is no Codex definition for 'breastmilk substitute', but is very strongly of the view that the different roles of follow-up formula for older infants and [name of product] for young children need to be reflected throughout the revised Standard. This is clear in the composition provisions specified with [name of 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. These different roles need to be clear within the preamble and the labelling requirements of the standard such that these different roles are clear to all, and in particular to consumers via information provided on product labels.

Provision of sufficient information to consumers to permit informed product choice is also an important consideration. INC advocates for nutrition claims to be specifically permitted in the revised standard for follow-up formula for older infants and nutrition and health claims to be specifically included in the revised standard for [name of product] for young children.

INC wishes to raise the following issues for consideration which fall outside of the recommendations presented in the agenda paper.

1. Footnote 20 applicability to [name of product] for young children. INC has identified an important issue in this regard and is very concerned that this footnote on optional addition of DHA for follow-up formula for older infants may be applied to [name of product] for young children. Two options for additional text to resolve this issue are included in our response to Recommendation 2.

2. Protein Quality Criteria footnote in the essential composition of Section B. INC proposes this is reworded slightly to better accommodate the adoption of new methods.

3. Statement on sodium chloride in the essential composition provisions of Section B. INC proposes that the wording of the statement be reviewed so that it covers all sources of added sodium and not just sodium chloride.

Expanded comments for (2) and (3) are provided on these topics below. These comments are then followed by INC responses to the recommendations in the order that they are listed in the agenda paper.

Finally, INC notes that there are some numbering discrepancies with Section B Part 3 ESSENTIAL COMPOSITION AND QUALITY FACTORS in the Proposed Draft Standard in the Agenda Paper and in the INC response we refer to the sections as they are numbered in the Agenda Paper.

Issues identified not covered by recommendations

2. Protein Quality Criteria (Section B)

INC recommends an amendment to the footnote** relating to protein quality in Section B of the revised standard as follows:

Protein**)

) ~~The quality of protein shall not be less than 85% of that of casein~~. The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future. **The quality of protein shall not be less than 85% of that of casein when determined by PER or comparable criteria where another method is used.

Rationale

This is because the protein quality measure 'of not less than 85% of that of casein," is appropriate for PER which is considered to be outmoded. The general consensus is that it should be replaced as soon as alternative method(s) deemed to be suitable become available. For alternative methods to be able to be used in practice, the protein quality criteria applied may need to be modified to be meaningful in the context of the particular method concerned. INC therefore proposes the revised wording as an interim measure until such time as FAO completes its review.

3. Statement on sodium chloride

INC requests that the clause 'No sodium chloride should be added to [name of product] for young children' be reconsidered in favour an alternative statement that 'sodium addition should be avoided where possible to minimise sodium levels' or a maximum level set or expressed in such a way that it does not restrict the sodium inherently present in these products from milk.

Rationale

INC supports a measure to limit the amount of sodium in [name of product] for young children.

However notes the following inconsistencies which could be addressed by the alternative statement proposed:

1. The prohibition of sodium chloride conflicts with the permission for its use in in CAC/GL 10-1979. Nutrient compounds are included on this advisory list if they meet certain criteria, i.e. they are shown to be safe and appropriate for the intended use, they are biologically available, they comply with specific purity criteria and they are shown to be stable in the food(s) in which they are intended to be used (see section 2 of the guidelines). While sodium chloride is not commonly used in the manufacture of these products there can be applications for which it is required and removing the specific prohibition for sodium chloride eliminates this conflict.

2. CODEX STAN 156-1987 currently permits the addition of certain food additives to Follow-up formula. These additives have a technological need and have undergone safety assessment by JECFA. A number of food additives within the category 'pH adjusting agents' are sodium salts, i.e. Sodium hydrogen carbonate, Sodium carbonate, Sodium citrate, Sodium hydroxide. The current standard requires these to be added according to GMP and provided the sodium maximum specified is not exceeded. The alternative statement proposed by INC makes it clear that these sodium containing food additives should only be added when needed and in the minimum quantities required.

INC considers that the outcome sought of constraining the levels of sodium is more appropriately covered by a statement to avoid, rather than prohibit the addition of sodium/sodium chloride. INC therefore recommends an approach is taken similar to the approach taken in the Codex Infant Formula standard regarding fructose and sucrose addition which uses wording 'should be avoided' and reason for this.

"Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance."

INC refers to the guiding principles for the revision of the standard for young children 12-36 month, including accommodation of cows' milk, infant formula and breast milk. Whole cows' milk sodium levels range between 76 mg/100kcal and 124 mg/100kcal* (Jensen R 1995). Reduced fat milk and skim milk levels are higher again. Average levels in whole milk are approximately 95 mg/100kcal (Sep 2016 eWG paper), however this does not account for variation.

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS (6-12 MONTHS)
1.5 Protein
1.5.1 Minimum protein level in follow-up formula for older infants

Recommendation 1:
That CCNFSDU agree to revise the protein requirements as follows:

1. that a minimum protein level of 1.6 g/100 kcal is established and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/ 100 kcal.
2. that the minimum protein value for soy protein isolate is retained, and that the second sentence in footnote 5 is amended to be consistent with the first (include 'or goats'').
3. that the current minimum for follow-up formula based on hydrolysed protein is retained.
4. that the two sentences relating to the clinical evaluation of formula based on non-hydrolysed milk protein containing less than 1.8 g /protein/100 kcal and formula based on hydrolysed protein containing less than 2.25 g/protein/100kcal in footnote 6 are combined.

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

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

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

[3)] For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

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

[5)] The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' **[or non-goats']** milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of **[**2.25 g/100 kcal (0.5**4** g/100 kJ)**]** applies.
~~[6)] Follow-up formula based on non-hydrolysed milk protein containing [1.61 – 1.8 g] protein/100 kcal should be clinically evaluated by a competent national and/or regional authority. Follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].~~
[6)] Follow-up formula based on non-hydrolysed milk protein containing **[less than 1.8 g]** protein/100 kcal **[(0.43 g/100 kJ)]** and follow-up formula based on hydrolysed protein containing less than [2.25 g

protein/100 kcal] **(0.54 g/100 kJ)** should be clinically evaluated by a competent national and/or regional authority.]

INC comment
INC supports minimum protein level of 1.6g/100kcal, and for this minimum to be stated in table.

INC also supports the insertion of the words 'or non-goats' in footnote 5 as proposed by this recommendation.

However INC has concerns about the wording of Footnote 6 from two perspectives. Firstly that clinical evaluation is not always needed for scientific substantiation, and secondly that the proposed wording does not accurately reflect the role of national/regional authorities. INC suggests the following modification:

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

Rationale
Taking into account that in some low income countries intake of complementary foods with sufficient quality and quantity may be low, INC supports a footnote requiring that follow up formulas containing levels of protein less than 1.8g/100kcal be scientifically substantiated in order to guarantee safety and suitability for the targeted population in the context of the overall local/regional diet.
The following should be considered:

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

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

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

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

3. .More precisely on its proposal that follow up formula should be clinically evaluated "**when needed**", INC considers that, as a wider body of evidence becomes available, clinical evaluation may become redundant, therefore 'when needed' is important to reflect this.

References

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

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

1.6 Optional addition: Docosahexaenoic acid

Recommendation 2:
That CCNFSDU agree:
that the minimum in the footnote for the optional addition of docosahexaenoic acid is set to 13 mg/100kcal (3.1 mg/100 kJ).
that the agreed GUL of 0.5% of total fatty acids is converted to 30 mg/100 kcal (7.9 mg/100 kJ).

Docosahexanoic acid 20)

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

20) If docosahexanoic acid (22:6n-3) is added to follow-up formula, a minimum level of [**13 mg/100 kcal (3.1 mg/ 100 kJ)**] should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as docosahexaenoic acid. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions**,** as appropriate for the nutritional needs of their local population.

INC Comments

INC supports the optional addition of docosahexanoic acid (22:6n-3) and that there should be no mandatory addition of arachidonic acid (20:4 n-6) when docosahexanoic acid (22:6n-3) is added.

INC has a preference that no minimum docosahexanoic acid (22:6n-3) level be set to apply when added, however, in the spirit of compromise, INC can accept a minimum of 13mg/100kcal as well as the revised expression of the GUL as proposed, noting that the per 100 kJ figure requires updating.

Also, INC supports that "Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their local population"

INC's preferred wording for the footnote is therefore as follows:

20) If docosahexaenoic acid (22:6n-3) is added to follow-up formula, the addition of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3), is optional. If eicosapentaenoic acid is added, its content should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their local population.

Additionally, INC is concerned that the requirements of the footnote may be unintentionally applied to [name of product] for young children and proposes additional text to clarify.

Rationale

INC supports the optional addition of docosahexanoic acid (22:6n-3) (DHA), taking into consideration that several expert opinions have:

- Established nutritional requirements for DHA and concluded that the dietary DHA intake may be low in older infants, consequently support supplementation of older infant's diets, including follow-up formula for older infants (AFSSA, 2010; FAO, 2010; EFSA, 2013; Koletzko, 2013; EFSA, 2014);
- Recommended DHA intake levels associated with beneficial health outcomes (AFSSA, 2010; FAO, 2010; EFSA, 2014).

INC prefers not to set a minimum level where DHA is added as an optional ingredient due to the global variability of dietary DHA intakes, as highlighted by Brenna (2008).

However, in the spirit of compromise INC can accept the minimum level proposed in this recommendation of 13mg DHA/100kcal] when DHA is added.

INC notes that whilst the GUL per 100kcal has been revised to 30 mg/100kcal, the GUL per 100kJ requires similar update from 7.9 mg/100kJ to 7.2 mg/100kJ

Regarding ARA, INC considers that there is insufficient scientific consensus to define strict criteria for the levels of ARA when DHA is added (ENA, 2012; EFSA, 2013; EFSA, 2014) and requests that the mandatory link between DHA and ARA be a matter for national/regional authorities to determine.

INC notes the footnote is intended to provide guidance to national and regional authorities as to the level of DHA that should be reached for older infants and additional requirements for ARA and EPA when DHA in added on a voluntary basis.

Optional ingredients listed in [3.1.3] Section A are permitted as Optional Ingredients for [name of product] for young children by Section B 3.2.1 however, INC is very concerned that the footnote may be unintentionally applied.

DHA is recognised as a nutrient that can be insufficient in the diet of some young children but not ARA (Suthutvoravut et al 2015, EFSA, 2013 and EC, 2016) and that [name of the product] for young children is a suitable vehicle for delivery of DHA to their diets. Young children consume an increasing diversified diet, with DHA sources coming from other parts of the diet, and mandating the same minimum level if added is not warranted. And the mandatory addition of ARA would negatively impact on the cost, palatability and keeping qualities of these products. The latter is more of an issue for these products than for Follow-up Formula for older infants as they are consumed in lesser amounts meaning packs take longer to consume post-opening.

Hence, INC proposes that this is clarified either in the footnote (Option 1) or in Section B 3.2.1 (Option 2) by addition of text highlighted as bold text below:

Option 1

20) If docosahexaenoic acid (22:6n-3) is added …. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their local population. **This footnote is not applicable to [name of product] for young children.**

Option 2

3.2.1 In addition to…Optional ingredients listed in [3.1.3] Section A are also permitted. **In the case of docosahexaenoic acid (22:6n-3) footnote 20 is not applicable and a principle based approach applies to level of addition**.

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

2.4 Minimum total fat

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

INC Comment
INC supports a minimum level for fat of 3.5 g /100 kcal.

2.5 Carbohydrate
2.5.2 Maximum level available carbohydrate

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

INC reiterates its previous position to **support a maximum level of available carbohydrates at 14 g/100 kcal (3.3g/100kJ)** instead of 12.5 g/100 kcal (3.0g/100kJ). This is aligned with several eWG member responses, expert opinions (Suthutvoravut et al 2015, ESPGHAN), and nutrient requirements for young children to support a level that is scientifically substantiated.

In addition, INC maintains that the maximum carbohydrate level of 14 g/100 kcal

- Meets all of the objectives of the eWG and achieves nutritionally balanced composition for [name of product] for young children.
- Is aligned with the approach taken to set the maximum carbohydrate level in infant formula and the revised requirements for follow-up formula for older infants as specifically noted by the eWG (i.e. based on residual energy calculations once the minimum amounts of protein and fat were established)
- Does not significantly increase the potential amount of sugars other than lactose that could be added to [name of the product] for young children (difference of 0.3 g/100 kcal between maximum levels of carbohydrates of 12.5 or 14 g/100 kcal). Limits for available carbohydrate and sugars should be assessed independently.

Rationale

INC has highlighted what we believe to be the key objectives of the eWG and have provided justification in support of the level of 14g/100kcal:

1. To consider the contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children

INC response:

Regarding reference to cows' milk levels for carbohydrate, INC does not support that the maximum carbohydrate for [name of product] for young children should be based solely on cow's milk. INC would like to remind the committee that the protein content of cows' milk is much higher at an average of 5.4 g/100 kcal and 7.3 g/100 kcal (CP2, 2016) for full fat and reduced fat cows' milk respectively, therefore using cows' milk as a reference only for carbohydrates would not be appropriate since the minimum protein has been set at a much lower 1.8 g/100 kcal. Thus, it is even more imperative to permit flexibility and consider all macronutrients together with respect to their contribution to energy.

As macronutrients should not be considered in isolation, we consider calculation of the maximum carbohydrate level can be reviewed now that the CCNFSDU has agreed on a minimum protein level of 1.8g/100kcal and a minimum fat level of 3.5g/100kcal. With these levels agreed, and in line with previous modelling by the CCNFSDU for infant formula and follow-up formula for older infants, the residual carbohydrate can be calculated. The result is 15.3g carbohydrate/100kal. Therefore, the proposed level of 14g provides a conservative maximum of carbohydrate.

2. To establish a max carbohydrate limit for [name of product] for young children that results in formulations of product which would could be low fat OR low protein but NOT both

INC response:

The INC modelling exercise clearly demonstrates it is not possible to formulate a product with BOTH low protein (1.8g/100kcal) and low fat (3.5g/100kcal) with a maximum carbohydrate level of 14g/100kcal. When protein is set at 1.8g, the residual fat is 4.1g/100kcal. And when fat is set at 3.5g, the residual protein is 3.1g/100kcal. Thereby, satisfying the eWG objective to avoid products with both low fat and low protein.

TABLE 1: Modelling exercise showing the effect on residual fat and protein levels (in bold) when the carbohydrate is set at 14g/100kcal alongside the agreed CCNFSDU minimum fat (3.5g/100kcal) or protein (1.8g/100kcal) levels

	Product 1		*Product 2*	
Low protein	*g/100 kcal*	*% E*	*g/100 kcal*	*% E*
Carbohydrate	14	56	14	56
Fat	3.5	31.5	**4.1**	36.8
Protein	**3.1**	12.5	1.8	7.2

3. Attention should be paid to restrictions on sugars (mono-and disaccharides) and other sweet tasting carbohydrates

INC response:

There seems to be confusion with respect to the science regarding carbohydrates and sugars. The permitted *level* of available carbohydrate is a different provision than the *type* of permitted carbohydrate. Concerns about added sugar cannot simply be addressed by reducing the maximum carbohydrate level and this has been acknowledged by the chairs of the eWG. More precisely, the potential difference in amount of sugars others than lactose, between a product with a level of carbohydrates of 12.5 vs. 14 g/100 kcal would be insignificant (difference of 0.3 g/100 kcal sugars when calculated in accordance with recommendation 5 *'mono-and disaccharides, other than lactose, should not exceed 20% of available carbohydrate'*). In the interest of young child health, INC supports limiting added sugars in [name of the product] for young children and believes regulating the *type* of carbohydrate will further address any concerns about the nutritional profile of the products. Limits for available carbohydrate and sugars should be assessed independently.

4. INC notes the comment by the Committee, "*that breast milk, formulas for infants and cow's milk are all suitable for the young child age group, and as such any levels specified in the standard would need to accommodate these foods*."

INC response:

Both the infant formula standard and revised requirements for follow-up formula for older infants contain 9-14g/100kcal available carbohydrate. Therefore, the proposed maximum carbohydrate level of 14g/100kcal (3.3g/100kJ) accommodates more closely these foods, also suitable for young children as advised by the Committee.

References

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

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

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

Recommendation 5:
That CCNFSDU:
1. agree to establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates.
2. agree that sweet tasting carbohydrates are restricted in accordance with the amended footnote 4 below.
3. considers the need to limit the addition of non-carbohydrate ingredients with the purpose of imparting a sweet taste.

Carbohydrates
Available cabohydrates4)

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

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

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

INC comments
INC favours having the maximum added sugar expressed as a % of energy, but for the purpose of responding to this recommendation, INC supports a maximum of added sugars (excluding lactose) of 20% of available carbohydrates (which is about **10% <u>total energy</u>**). This is in line with limits on sugars level recommended by the WHO (WHO, 2015).

INC strongly supports restricting added sugars other than lactose and can accept the use of 'mono- and disaccharides' in place of the word 'sugars' as proposed in this recommendation in alignment with the definition of sugars in CAC/GL 2-185 Guidelines on Nutrition Labelling. However INC finds the last two sentences proposed for footnote 4 confusing and not adding value. Therefore INC suggests deleting them, footnote 4 would then read:

> 4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, should not exceed 20% of available carbohydrate~~ucrose and/or fructose [and/or other carbohydrates contributing to the sweet taste of [name of product]] should not be added, unless needed as a carbohydrate source. [Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]~~

<u>Rationale</u>
The third sentence is redundant as the second sentence already requires all mono- and disaccharides present not to exceed the stated limit. This therefore encompasses all mono- and disaccharides present in any ingredients used. If this text is retained INC's preference would be to avoid the use of the term sugar alongside the use of the term mono and disaccharides and suggests the following alternative wording:

4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, should not exceed 20% of available carbohydrate, including those naturally present in honey, syrups, fruit juices and fruit juice concentrate.

In the sentence: [Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.], the wording "unless needed as a carbohydrate source" is subject to interpretation and is redundant since the addition of sucrose and fructose is restricted by the limit to be set for mono- and disaccharides.

Furthermore, it appears that the text relating to sucrose and fructose has been carried over from the infant formula standard without adequate regard for the rationale for its inclusion. In the Codex Infant Formula standard is states that: "Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance." However, once infants begin consumption of complementary foods there is no reason to continue this restriction. EFSA (EFSA, 2014) commented on this as follows: "Because complementary food will provide other glycaemic carbohydrates than lactose, there is no reason to restrict their [sucrose and fructose] use in follow-up formula as long as certain maximum levels are not exceeded." The rationale to exclude fructose for young infants does not extend to young children who are encouraged to consume fruits for example that contain fructose.

Finally, INC recommends against inclusion of text relating to non-carbohydrate ingredients added for the purpose of imparting a sweet taste on the basis that:

- While mono- and disaccharides are well defined, the wording "other carbohydrates contributing to the sweet taste" is vague and challenging (aside from the fact that it is somewhat surprising to have a provision on non-carbohydrate ingredients in a section on carbohydrates). Sweetness can be defined relative to sucrose (ESPGHAN, 2017) but sweet taste is influenced by different factors (e.g. genotype or age) (ESPGHAN 2017, Mennella et al 2016) and also food matrix.
- The use of such ingredients is already controlled by the absence of permissions as Food Additives in Codex STAN 192-1995, so inclusion or text covering their addition in this proposal is not necessary

References

EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014; 12(7) 3760

ESPGHAN Committee on Nutrition: Sugar in infants, children and adolescents: A position paper of the ESPHAN Committee on Nutrition; JPGN 2017, DOI: 10.1097/MPG0000000000001733

Mennella J,. Bobowski N., Reed D: The development of sweet taste: From biology to hedonics; Rev Endocr Metab Disord 2016 DOI 10.1007/s11154-016-9360-5

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

Recommendation 6:
That CCNFSDU agree that the percentage limit for sugars [and other carbohydrates contributing to the sweet taste] is converted to an absolute amount based on the energy density (g/ 100 kcal and g/ 100 kJ) of product for young children once a decision is made on the maximum level of available carbohydrates.

INC comments
INC supports the conversion of the percentage limit for sugars to an absolute amount based on energy density of product once decision is made on the maximum level of available carbohydrates providing this is not less than 20% of available carbohydrate as proposed in recommendation 5.

INC also proposes [Other non-carbohydrate contributing to the sweet taste) are not included for reasons detailed in response to recommendation 5.

2.7 Calcium-to-phosphorous ratio

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

INC Comment
INC supports this recommendation for no calcium-to-phosphorous ratio to be included.

2.8 Vitamin D

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

Vitamin D

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

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

INC Comment
INC supports this recommendation for min of 1.5 and max of 4.5ug/100kcal.

3. PREAMBLE

Recommendation 9:

1) That CCNFSDU agree to the approach proposed by the Codex Secretariat and WHO, that being to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA resolutions, noting this approach to the Preamble would replace the need to list or reference these documents and resolutions within different sections of the Standard itself.
2) That CCNFSDU agree to the following Preamble statement proposed by the Codex Secretariat and WHO, and select the preferred wording from that presented in square brackets:

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

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant

*national/regional legislation, and take into account, [**as appropriate**,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / **supported**] by member states [**may also**] provide guidance to countries in this context.*

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

INC Comment
INC can support the approach outlined in part 1 of this recommendation provided the word endorsed is inserted as shown:

That CCNFSDU agree to the approach proposed by the Codex Secretariat and WHO, that being to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA **endorsed** resolutions, noting this approach to the Preamble would replace the need to list or reference these documents and resolutions within different sections of the Standard itself.

INC supports the following wording for the preamble statement:

*The Codex Alimentarius Commission acknowledges the need to [**protect and support ~~/recognize~~**] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [**~~necessary /~~ appropriate**], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods. **While** these products **are not formulated nor intended as substitutes for human milk** they should not discourage **continued** breastfeeding.*

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

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

<u>Rationale</u>

INC members support the aims of the International Code of Marketing of Breast-milk Substitute (1981) ('WHO Code') and have worked with both the Australian and New Zealand governments and other stakeholders to develop and implement local interpretations of the WHO Code. These are the Manufacturers and Importers Agreement ('MAIF Agreement') for Australia and The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula for New Zealand. In alignment with these local interpretations of the WHO Code, INC supports the approach to formulas for infants (inclusive of 6-12m age category) in this recommendation, but not the wording used in relation to [name of product] for young children.

INC considers that, in addition to the selected text sought from the options provided in square brackets in the text provided in the recommendation, as shown above, the last sentence of the first

paragraph needs to be modified as indicated (last part of text amended and original sentence split into two sentences)This is needed to reflect the clear differentiation of roles of [name of the product] for young children compared to Follow-up formula for older infants compared that has been established during this standard review. From a safety perspective it needs to be clear that various products referred to for young children are not formulated or intended as substitutes for human milk.

INC questions the addition of the sentence "Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context." As the broader topic of WHO policies and Codex mandate will be considered at the next session of the Codex Alimentarius Commission (CAC41) this addition may prove premature.

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

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

5.2 Scope – Individual Provisions

5.2.1 Scope – Section 1.1

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

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

INC comment
INC supports this recommendation on the basis that text stating, "It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)" is covered in preamble as per recommendation 9.

5.2.2 Scope – Section 1.2

Recommendation 11:
That CCNFSDU agree to the following statement for Section 1.2:

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

INC comment
INC does not oppose addition of 'labelling,' but does not support the inclusion of the term 'analytical.' INC would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants – and as such do not need to be listed in this high level overview.

5.2.3 Scope – Section 1.3

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

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

INC comment
In line with the Chair's conclusion, INC supports this recommendation and favours the word "shall" instead of "should" as this is more consistent with the terminology used in the labelling section of the Standard.

5.2.4 Scope – Section 1.4

Recommendation 13:
That CCNFSDU agree to:

- include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper.

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

INC comment

- Overall INC accepts, with restriction to the documents listed within the proposed wording provided by INC above in relation to Recommendation 9.1

INC supports the deletion of provision 1.4 for follow-up formula for older infants from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant, in line with Recommendation 25

5.3 Labelling – Introductory Paragraph
5.3.1 Ingredient and nutrient declarations/claims

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

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

INC comment
While INC supports the text provided in the recommendation for the introductory paragraph to the Labelling section, including a reference to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), INC believes voluntary declarations about the presence or not of nutrients and ingredients (e.g. "low-protein", "lactose free", "contains DHA"), should be permitted on follow-up formula for older infants. INC therefore suggests:

- adding the following text in bold to the <u>introductory paragraph</u> to the Labelling Section for follow-up formula for older infants (Section A)

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

claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.
The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to this standard.

- adding the following 2 provisions under section 9. Labelling

(New) 9.1 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, Nutrition claims may be permitted for the products that are the subject of Section A of this standard.

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for older infants are adopted by Codex or available at national level.

Rationale

The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) clearly describe what are **Nutrient claims**. They encompass **Nutrient content claims** and **Nutrient comparative claims** as defined below:

2.1 Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

2.1.1 Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: “source of calcium”; “high in fibre and low in fat”.)

2.1.2 Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods. (Examples: “reduced”; “less than”; “fewer”; “increased”; “more than”.)

Health claims are a separate category than **Nutrition claims** and are defined in that same Guidelines as “any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health”, they include:

- Nutrient function claims
- Other function claims
- Reduction of disease risk claims

INC supports authorizing Nutrition claims on follow on formula for older infants but not Health claims.

- The valid role of nutrition and health claims has been recognized by national legislation in a number of countries. Nutrition claims such as “low-protein”, “lactose free”, “contains DHA” are already allowed on labels for foods intended for healthy infants in a number of countries.

- The Global Strategy for Infant and Young Child Feeding states, “The expert consultation recognized that some mothers will be unable to, or choose not to, follow this recommendation (to breastfeed); they should be supported to optimize their infants’ nutrition.” Nutrition claims on formula are a sensible way to encourage optimized nutrition for older infants who are not breast-fed.

- Older infants need nutrient dense foods due to their high energy and nutritional needs combined with a limited stomach capacity, but most adult food is not able to provide such density.

- It is crucial that parents and caregivers are able to make appropriate and informed choices about feeding their older infants. Statements about the nutrients and ingredients in the product provide valuable information that helps consumers make these choices.

- Restricting such way of communicating on follow-up formula for older infants would create unequal conditions of competition and could potentially lead to unhealthy food choices for older infants. Furthermore, foods not specifically intended for older infants and young children have to comply with less strict legislation in terms of contaminants, pesticides, hygiene, additives.

INC supports the use of nutrition claims for both mandatory and optional nutrients, noting that parents and caregivers are unaware of differences in nutrient categories.

Parents should also be informed of the quantity of daily reference value that is covered by nutrients provided. For this reason, Nutrition Reference Values should be established for this age group.

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

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

It is recommended that CCNFSDU agree that the progress of reviewing this Standard should not be delayed and that any consideration of NRVs (if established for this age group) and the purpose of such NRVs in the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985), including the need to consider whether any labelling provisions within Codex standards for foods for infants and young children need to be revisited if NRVs are adopted by Codex, should form part of the ToR for a NRV working group.

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

INC comment
INC does not support this recommendation and instead suggests inserting a reference to NRVs for older infants in the section 5.3.1 as described in INC comments on recommendation 14 and which reads:

> (new) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for older infants are adopted by Codex or available at national level.

Rationale
INC strongly supports the establishment of NRVs-R (*Nutrient Reference Values – Requirements)* for older infants. The establishment of harmonised NRVs-R could inform:

1. **Compositional requirements / guide micronutrient composition**
   This is particularly important for optional nutrients for which compositional requirements (i.e. minimum, maximum, GULs) are not established in Codex standards or national legislation.

2. **Nutritional labelling**
   Where NRVs-R are established, numerical information could be expressed as a % of the NRV-R per 100 g or per 100 ml or per package if the package contains only a single portion. Conveying information regarding the nutrient content of a food on the label enables consumers to make informed nutritional choices.

3. **Nutritional Content Claims on food for older infants and young children:**

The establishment of NRVs-R for older infants could support the assessment of nutritional claims. The Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) lays down provisions for nutrient content claims based on a minimum % NRV. For example, a 'source' claim could be made for protein if the food meets one of a number of criteria, i.e. 10% of the NRV per 100 g (solids); 5% of NRV per 100 ml (liquids); 5% of NRV per serving etc.

Noting that the work on NRVs for older infants is likely to be a lengthy process, INC considers that the revised Standard should include text, similar to the approach taken for protein quality, which makes provision for use of nutrition claims based on NRVs when they become available, rather than the Standard needing to be revisited at this time.

5.4 Labelling - Name of the Product

Recommendation 16:
That CCNFSDU agree to the following text for Section 9.1 – The Name of the Product, and select its preferred option for provision 9.1.4, including the text within square brackets.

9.1 The Name of the Product

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

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

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

9.1.4 OPTION 1: Split provision 9.1.4 into two:

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

9.1.4(b) If [name of plant] is the only source of protein [*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].
[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

OR

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

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

INC comment
INC supports this recommendation with, addition of "or regional" to 9.1.2; use of option 1 for 9.1.4 and use of 'shall' rather than 'may' in 9.1.5.

5.5 Labelling - List of Ingredients

Recommendation 17:
That CCNFSDU agree to the following text for Section 9.2 – List of Ingredients.

9.2 List of Ingredients

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

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

INC comment
INC agrees the phrase 'including optional ingredients' is redundant.

INC is not opposed to the inclusion of the sentence "Food additives may also optionally declare the INS number.

5.6 Labelling – Declaration of Nutritive Value

Recommendation 18:
That CCNFSDU agree to the following drafting text for Section 9.3 – Declaration of Nutritive Value.

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

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

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

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

INC Comment
INC opposes this drafting on the basis that operationally, manufacturers consider it easier for both the consumer and for labelling to present one mandatory column of per 100 ml with the option to present further information in additional columns as per 100 grams and/or per 100kJ/kcal.

INC recommends the following wording:

9.3 Declaration of Nutritive Value

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

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

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

c) In addition, the declaration of nutrients in a) and b) per 100 grams or per 100ml concentrated liquid as sold and/or per 100 kilocalories (or per 100 kilojoules) is permitted in additional columns."

5.7 Labelling – Date Marking and Storage Instructions

Date Marking and Storage Instructions

9.4 Date Marking and Storage Instructions

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

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

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

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

Recommendation 19:

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

INC comment

INC agrees to this recommendation in principal, but feels it would be appropriate to review after the revised text is known.

5.8 Labelling – Information for Use

Recommendation 20:

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

9.5 Information for Use

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

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

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

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

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

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

INC comment

INC supports this recommendation but feels that the wording of 9.5.2 is awkward and proposes alternative wording as follows:

9.5.2 Adequate directions for the appropriate preparations and use of the product shall appear on the label. This includes statements about the product's storage and disposal after preparation, for example, that product remaining after feeding should be discarded.

9.5.6 INC would prefer that the text '[is not to be used as a sole source of nutrition].' is retained rather than deleted, but can also understand the eWG's view that it is redundant given it is clear that infants should receive complementary foods in addition to the product.

5.9 Labelling – Additional Labelling Requirements

Recommendation 21:
The CCNFSDU agree to the following text for Section 9.6, that the Committee consider the text presented within the square brackets included within the individual provisions.

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

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

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

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

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

~~[~~9.6.2 The label shall have no pictures of infants and women nor any other picture[,] ~~or~~ text[,] ~~which idealizes the use of follow-up formula. The label shall have no pictures images, text or other representation~~ that might:

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

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

9.6.2.3 recommend or promote bottle feeding;

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

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

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

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

INC comment
INC can support this recommendation with modifications as detailed below, but would prefer this section to be more concise and not so similar to the infant formula standard to provide better differentiation between infant formula and follow-up formula for older infants.

9.6.1 INC supports removing (d)

9.6.2.1 to 9.6.2.4 INC supports the changes

9.6.2.5 INC strongly opposes the addition of "[9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]"

9.6.3 INC Agrees

9.6.4 INC very strongly opposes some of the proposed additional wording at the end of this provision.

Rationale

INC does not support requirements which are more stringent than those included in the Infant Formula Standard CODEX STAN 72-1981 as is the case for 9.6.2.5 as well as aspects of 9.6.4 as proposed.

9.6.2.5 as proposed could preclude the use of the terms 'Halal,' or 'Organic' and other similar product descriptions which consumers find valuable to inform product choices based on religious or cultural or other personal principles.

With respect to 9.6.4, INC very strongly opposes the additional wording "[in particular as to the text, images and colours used]", which is at the end of this provision. With this deletion 9.6.4 would read as follows:

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

INC supports a clear differentiation between these different product categories. However, we consider this is best achieved via the text differentiation already established within the proposed labelling requirements and the additional text INC seeks to be added to Section B 9.5.6 to reduce the risk of (name of product) for young children being confused with other formula products given the safety risk posed by these products being fed to infants. The addition of requirements as to images and colours used is both unnecessary and unhelpful. We believe that the proposed additional factors of "images" and "colours" are very subjective, and open to different interpretations.

- The labelling features currently applied typically include clear age labelling, staging, and name of product as prominent features. The proposed revised standard prescribes distinctively different product names and other text to be included on labels which provide clear product differentiation, for example product specific information for use. As such, text differentiation is already stipulated.
- On images, Clause 9.6.1 in Section B is proposing to legislate a prohibition on images of feeding bottles in (name of product) for young children, which INC supports. We are concerned about the different possible interpretations with respect to other images and that these could lead to unintentional consequences relating to trademarks and intellectual property.
- INC has similar concerns on possible different interpretations of use of different colours – does this relate to label background colour, ribbon on label or text colour? Adding such a requirement could lead to substantially more colours on shelf, and potentially lead to consumer confusion.

INC supports a clear differentiation between these different product categories and this being specified as a requirement, but does not support the additional wording, "in particular as to the text, images and colours used," set out at the end of proposed text for 9.6.4. We consider that clear product differentiation is already established by the text requirements within proposed labelling provisions (including additional text sought by INC noted above), and the prohibition on using images of feeding bottles proposed in 9.6.1.

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

6.2 Scope – Individual provisions
6.2.1 Scope – Section 1.1

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

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

INC comment
INC supports this wording provided text stating, "It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)" is covered in preamble.

6.2.2 Scope – Section 1.2

Recommendation 23:
That CCNFSDU agree to the following statement for Section 1.2:

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

INC comment
INC does not oppose addition of 'labelling,' but does not support the inclusion of the term 'analytical.' INC would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants – and as such do not need to be listed in this high level overview.

6.2.3 Scope – Section 1.3

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

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

INC comment

In line with the Chair's conclusion, INC supports this recommendation and favours the word "shall" instead of "should" as this is more consistent with the terminology used in the labelling section of the Standard.

6.2.4 Scope – Section 1.4

Recommendation 25:
That CCNFSDU agree:

- to include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper.

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

INC comment

- Overall INC accepts, with restriction to the documents listed within the proposed wording provided by INC above in relation to Recommendation 9.1
- INC supports the deletion provision 1.4 for follow-up formula for older infants from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant, in line with Recommendation 13

6.3 Labelling – Introductory Paragraph
6.3.1 Ingredient and nutrient declarations/claims

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

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

INC comment
While INC supports the text provided in the recommendation for the introductory paragraph to the Labelling section, including a reference to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), INC believes that Nutrition and Health claims should be authorized for (Name of Product) for Young Children. Nutrition and Health claims, such as nutrient function claims, should be permitted whenever the nutrient is present at a sufficient amount to achieve the intended effect, and the effect is scientifically substantiated:

INC supports voluntary declarations about nutrients and ingredients and health claims being permitted on (Name of Product) for Young Children and therefore suggests:

- adding the following text in bold to the <u>introductory paragraph</u> to the Labelling Section for (Name of Product) for Young Children (Section B)

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

- adding the following 2 provisions under section 9. Labelling

  (New) 9.1 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, Nutrition and Health claims may be permitted for the products that are the subject of Section B of this standard provided, in the case of health claims, that they have been demonstrated in rigorous studies with adequate scientific standards.

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for young children are adopted by Codex or available at national level.

Rationale

The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) clearly describes what are Nutrient claims. They encompass Nutrient content claims and Nutrient comparative claims as defined below:

2.1 Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

2.1.3 Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: "source of calcium"; "high in fibre and low in fat".)

2.1.4 Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods.(Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

Health claims are a separate category than Nutrition claims and are defined in that same Guidelines as "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health", they include:

- Nutrient function claims
- Other function claims
- Reduction of disease risk claims

INC supports authorizing both Nutrition and Health claims on (Name of Product) for Young Children.

- The valid role of health and nutrition claims has been recognized by national legislation in a number of countries.

- The Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (Section 3.1 of Codex STAN 146-1985) already lays down detailed instructions to ensure that claims made for the foods are substantiated. Certain health and nutrition claims on labels for foods intended for healthy young children are already allowed in a number of countries.

- The Global Strategy for Infant and Young Child Feeding states, "The expert consultation recognized that some mothers will be unable to, or choose not to, follow this recommendation (to breastfeed); they should be supported to optimize their infants' nutrition." Nutrition and health claims on formula are a sensible way to encourage optimized nutrition for young children who are not breast-fed.

- Young children need nutrient dense foods due to their high needs combined with a limited stomach capacity, but most adult food is not able to provide such density. Furthermore, foods not specifically intended for older infants and young children have to comply with less strict legislation in terms of contaminants, pesticides, hygiene, additives.

- It is crucial that parents and caregivers are able to make appropriate and informed choices about feeding their older infants. Caregivers need access to this information and statements about the role of nutrients in the growth and development of young children provide valuable information that helps consumers make informed choices.

- Parents often compare these products with "general" foods that are allowed to use nutrition and health claims but that are not aligned with the Standard. Restricting such way of

communicating on products that are specially designed and manufactured for young children would create unequal conditions of competition and could potentially lead to unhealthy food choices for young children. Indeed, [name of the product] for young children is part of a diversified diet of the young children from 1 year of age. At this age, young children consume foods and drinks that parents choose from a variety of foods

- INC supports the use of nutrition and health claims for both mandatory and optional nutrients, noting that parents and caregivers are unaware of differences in nutrient categories. Parents should also be informed of the quantity of daily reference value that is covered by nutrients provided. For this reason, Nutrition Reference Values should be established for this age group.

- Because the composition of (Name of Product) for Young Children is less prescriptive than that of Follow-on formula for older infants previous, there is greater possibility to add optional ingredients. This is important from an innovation perspective and to ensure the best product is available to young children. Therefore, it is important that nutrition and health claims are permitted in order for manufacturers to be able to communicate on the innovations in their products.

For all these reasons INC believes it is important that specific provisions for Nutrition and Health Claims are included in this standard.

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

Recommendation 27:
That CCNFSDU note the preference of the eWG for revisiting nutrition claims on [name of product] for young children should NRVs be established and adopted by Codex for this age group.

That CCNFSDU agree that the progress of reviewing this Standard should not be delayed and that any consideration of NRVs (if established for this age group) and the purpose of such NRVs in the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985), including the need to consider whether any labelling provisions within Codex standards for foods for infants and young children need to be revisited if NRVs are adopted by Codex, should form part of the ToR for a NRV working group.

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

INC comment
INC does not support this recommendation and instead suggests inserting a reference to NRVs for young children in the section 6.3.1 as described in INC comments on recommendation 26 and which reads:

(New) 9.2 The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for young children are adopted by Codex or available at national level.

Rationale
INC strongly supports the establishment of NRVs-R (*Nutrient Reference Values – Requirements)* for young children. The establishment of harmonised NRVs-R could inform:

1. **Compositional requirements / guide micronutrient composition**
   This is particularly important for optional nutrients for which compositional requirements (i.e. minimum, maximum, GULs) are not established in Codex standards or national legislation.

2. **Nutritional labelling**
   Where NRVs-R are established, numerical information could be expressed as a % of the NRV-R per 100 g or per 100 ml or per package if the package contains only a single portion. Conveying information regarding the nutrient content of a food on the label enables consumers to make informed nutritional choices.

3. **Nutritional Content Claims on food for older infants and young children:**
The establishment of NRVs-R for young children could support the assessment of nutritional claims. The Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) lays down provisions for nutrient content claims based on a minimum % NRV. For example, a 'source' claim could be made for protein if the food meets one of a number of criteria, i.e. 10% of the NRV per 100 g (solids); 5% of NRV per 100 ml (liquids); 5% of NRV per serving etc.

Noting that the work on NRVs for young children is likely to be a lengthy process, INC considers that the revised Standard should include text, similar to the approach taken for protein quality, which makes provision for use of nutrition claims based on NRVs when they become available, rather than the Standard needing to be revisited at this time.

6.4 Labelling – Name of the Product

Recommendation 28:
That CCNFSDU agree to the following text for Section 9.1 – The Name of the Product, and select its preferred option for provision 9.1.4, including the text within the square brackets.

9.1 The Name of the Product

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

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

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

9.1.4 OPTION 1: Split provision 9.1.4 into two:

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

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

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

OR

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

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

INC comment
INC supports this recommendation with, addition of "or regional" to 9.1.2; use of option 1 for 9.1.4 and use of 'shall' rather than 'may' in 9.1.5.

6.5 Labelling – List of Ingredients

Recommendation 29:
That CCNFDU agree to the following text for Section 9.2 – List of Ingredients.

9.2 List of Ingredients

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

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

INC comment
INC agrees the phrase 'including optional ingredients' is redundant.

INC is not opposed to the inclusion of the sentence "Food additives may also optionally declare the INS number."

6.6 Labelling – Declaration of Nutritive Value

Recommendation 30:
That CCNFSDU agree to the following drafting text for Section 9.3 – Declaration of Nutritive Value for [name of product] for young children.

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

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

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

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

INC Comment
INC opposes this drafting on the basis that operationally, manufacturers consider it easier for both the consumer and for labelling to present one mandatory column of per 100 ml with the option to present further information in additional columns as per 100 grams and/or per 100kJ/kcal.

INC recommends the following wording:

9.3 Declaration of Nutritive Value

The declaration of nutrition information for (name of product) for young children must contain the following information which should be in the following order:

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

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

c) In addition, the declaration of nutrients in a) and b) per serving size and/or per 100 grams or per 100ml concentrated liquid as sold and/or per 100 kilocalories (or per 100 kilojoules) is permitted in additional columns."

6.7 Labelling – Date Marking and Storage Instructions

Date Marking and Storage Instructions
9.4 Date Marking and Storage Instructions
9.4.1 The ***"Best Before Date" or "Best Quality Before Date"*** ~~date of minimum durability (preceded by the words "best before")~~ shall be declared by the day, month and year ~~in uncoded numerical sequence~~ except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] ~~will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer~~. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]
In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.
9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.
Where practicable, storage instructions shall be in close proximity to the date marking.

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

INC comment
INC agrees to this recommendation in principal, but feels it would be appropriate to review after the revised text is known.

6.8 Labelling – Information for Use

Recommendation 32:
That CCNFSDU agree to the following text for Section 9.5 for [name of product] for young children and comment on the text still remaining in square brackets.

9.5 Information for use

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

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

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

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

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

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

INC comment
9.5.1 INC has no concerns with the wording changes.

INC agrees with provisions of 9.5.2 but feels that the wording is awkward. Alternative wording proposed:

9.5.2 Adequate directions for the appropriate preparations and use of the product must appear on the label. This includes statements about the product's storage and disposal after preparation, for example, that product remaining after feeding should be discarded.

INC seeks the removal of the word 'graphic' from 9.5.3 and for the removal of the redundant 'and' in 9.5.4.

INC requests that the following text is added to the end of 9.5.6: "It is not formulated as a substitute for human milk and is not suitable as a sole source of nutrition."

Rationale
The amendment proposed for 9.5.2 is aimed at improving the flow of the text.

The use of the word graphic in 9.5.3 is appropriate for follow-up formula for older infants which require more comprehensive mixing instructions but is not always needed for [name of product] for young children. INC therefore recommends that it is deleted.

The redundant and if 9.5.4 is shown here:

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

INC proposes that 9.5.6 is amended as shown:

[9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] [balanced] diet.] **it is not formulated as a substitute for human milk and is not suitable as a sole source of nutrition**.

INC request this additional text to ensure the different role of these products is clearly conveyed to consumers. This is important to ensure the safe and appropriate use of these products which provide only a limited number of mandatory nutrients compared to follow-up formula for older infants which mandates the addition of 32 nutrients.

6.9 Labelling – Additional Labelling Requirements

Recommendation 33:
That CCNFSDU agree to the following text for Section 9.6 for [name of product] for young children and that the Committee consider the text presented within the square brackets included within the individual provisions.

9.6 Additional Labelling Requirements

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

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

INC comment
INC can support this recommendation with modifications detailed below:

9.6.1 INC supports the inclusion

9.6.2
INC very strongly opposes the additional wording "[*in particular as to the text, images and colours used*]", which is at the end of this provision.

Rationale

INC supports a clear differentiation between these different product categories. However, we consider this is best achieved via the text differentiation already established within the proposed labelling requirements and the additional text INC seeks to be added to Section B 9.5.6 to reduce the risk of (name of product) for young children being confused with other formula products given the safety risk posed by these products being fed to infants. The addition of requirements as to images and colours used is both unnecessary and unhelpful. We believe that the proposed additional factors of "images" and "colours" are very subjective, and open to different interpretations.

- The labelling features currently applied typically include clear age labelling, staging, and name of product as prominent features. The proposed revised standard prescribes distinctively different product names and other text to be included on labels which provide clear product differentiation, for example product specific information for use. As such, text differentiation is already stipulated.
- On images, Clause 9.6.1 in Section B is proposing to legislate a prohibition on images of feeding bottles in (name of product) for young children, which INC supports. We are concerned about the different possible interpretations with respect to other images and that these could lead to unintentional consequences relating to trademarks and intellectual property.
- INC has similar concerns on possible different interpretations of use of different colours – does this relate to label background colour, ribbon on label or text colour? Adding such a requirement could lead to substantially more colours on shelf, and potentially lead to consumer confusion.

INC supports a clear differentiation between these different product categories and this being specified as a requirement, but does not support the additional wording, "in particular as to the text, images and colours used," set out at the end of proposed text for 9.6.2. We consider that clear product differentiation is already established by the text requirements within proposed labelling provisions (including additional text sought by INC noted above), and the prohibition on using images of feeding bottles proposed in 9.6.1.

7. DEFINITIONS
7.1 Product definition – follow-up formula for older infants

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

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

INC comment
INC supports this recommendation.

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

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

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

INC comment
INC supports the addition of **[formulated and] but queries if it is necessary to include the text in the last set of square brackets as follows:**

> **[Name of product] for young children** means a product specially **formulated and** manufactured for use as a liquid part of the **progressively** diversified diet of young children in order to contribute to the nutritional needs of young children

Rationale

INC supports the addition of the word "formulated" in the definition as it clarifies that the product is the result of specific and voluntary effort of the manufacturer to prepare a product for a specific intended use. Formulation refers to the phase of theoretical development of the product preceding the manufacturing itself (e.g. choice of specific ingredients when developing the product recipe).

With regards to the sentence "when nutrient intakes may not be adequate to meet nutritional requirements", INC considers this text is not needed. The shortened definition is clear and avoids the possible interpretations that a progressively diversified diet may not be sufficient to meet the nutritional requirements of young children or that the product can be used only when nutrient intakes are not adequate.

8. NAME OF PRODUCTS
8.1 Name of product for older infants

Recommendation 36:

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

INC comment
INC supports the proposal, but notes that If the name for the products for younger children is set as *Young Child Formulated Drink*, INC suggests consideration be given to amending the name for this category to *Older Infant Follow up Formula to achieve consistent approach with target group specified first.*

8.2 Name of product for young children

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

- Formulated drink for young children
- Young child formulated drink

INC comment
INC prefers Young *Child Formulated Drink* as it is shorter, and as for the name 'infant formula' the target population is specified at the start of the name.

So saying, INC is not strongly opposed to use of *Formulated Drink for Young Children* if the majority of member countries support this name.