REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156-1987)

(Chaired by New Zealand and co-chaired by Indonesia and France)

Second Consultation Paper
Submitters Response Form

June 2016

Please respond by **19th July 2016**

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Please provide your responses to the first consultation paper in the response form below. Note, to fill in a check box please right click on the box and select "Properties", under the "Default Action" sub-heading, select "Checked".

Name of Member Country/Organisation: Canada

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

In your responses to the following section please provide scientific justification for your response and where possible, references for the scientific rationale.

Protein

Protein

No agreement was reached on the establishment of a minimum or maximum protein value. Please provide scientific rationale to support your preferred value:

Protein

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	[1.8] or [1.65]	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39]	[0.84] or [0.72] or [0.60]	-

Minimum

☒ Codex Infant Formula standard 1.8 g /100 kcal 0.43 g /100 kJ	☐ 1.65 g /100 kcal 0.39 g /100 kJ

Please provide scientific justification and applicable references to support your response:

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

Maximum

☐ 3.5 g /100 kcal 0.84 g /100 kJ	☒ Codex IF std 3.0 g /100 kcal 0.72 g /100 kJ	☐ EFSA 2.5 g /100 kcal 0.60 g /100 kJ

Please provide scientific justification and applicable references for your response:

Canada continues to support a maximum protein level of 3 g/100 kcal in alignment with the Codex IF Standard. Canada would like to reiterate that it would be appropriate to have a cushion, since these are international recommendations that should take into consideration the resource limited settings where the

protein intakes and quality from complementary foods may also be limited. Please refer to the evidence reported in the response for the minimum above.

Footnote 3

Refers to the requirements of essential and semi-essential amino acids in follow-up formula:

[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); 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.

At present the draft standard does not contain an Annex I, please indicate whether you support inserting Annex I of the Codex Standard for Infant Formula of if you consider that further work is required.

☒ insert Annex I (or refer) to the Codex Standard for Infant Formula	☐ review the levels contained within the Codex Standard for Infant Formula.

If you consider that a review is required, please indicate the basis for this review.

We don't think that further review is required, however, we would like to mention that the quality of proteins used in the formulas particularly for the plant source of proteins, should be taken into consideration. For example, soy protein isolates (SPIs) prepared by different manufacturers or through different processes can be very different in their content of active protease inhibitors, which results in different protein bioavailability.

Footnote 6

The majority of the eWG supported retaining elements of footnote 6.

[[6)]Follow-up formula based on ~~non-hydrolysed~~ **intact** milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated

Regarding formulas based on **hydrolysed** protein, please state whether you think that all, or only those containing less than [2.25 g/100 kcal] should be clinically evaluated.

☒ All formulas based on hydrolysed protein should be clinically evaluated	☐ Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated

Please provide justification for your response.

Any hydrolysed formula should, in Canada's opinion, be clinically tested, but in young infants, not older infants consuming complementary foods. A growth and tolerance study should be conducted in newborn infants, starting at 0-14 days of age and continuing up to 112 days of age, since nutrient requirements are greatest during the first 16 weeks of life and any deficiency in the formula would be easily detected during this period. Clinical testing of all hydrolysed infant formula is required since protein hydrolysates are manufactured by different processes, resulting in products which may vary in nutritional adequacy. The formula used for clinical testing would be suitable for this age group, then the FUF using the same hydrolysed protein developed when adequate growth has been determined in young infants.

Regarding formulas based on **intact/non-hydrolysed** protein please note that your responses to these questions do not imply that you support a minimum of 1.8 g/100 kcal or 1.65 g/100 kcal. They will be used to refine the wording in square brackets if the eWG cannot come to agreement on a minimum value.

Please state whether you support the proposal to amend the reference these types of formulas to **intact milk protein**.

☒ intact milk protein	☐ non-hydrolysed milk protein

Please provide justification for your response.

Intact milk protein is clearer and less confusing than the non-hydrolysed terminology.

Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required for any formulas based on intact/non-hydrolysed milk protein?

☐ Yes, all formulas containing 1.65-1.8 g/100 kcal require clinically evaluation	☒ Yes, all formulas containing 1.65-2.0 g/100 kcal require clinically evaluation	☐ no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal

Please provide justification for your response.

Based on our experience for the premarket notification of infant formulas, we have required clinical trials for all infant formulas containing protein in the range 1.65 to 2 g/100 kcal. Canada makes the decision on

a case- by- case basis, e.g., if the formula is new to the Canadian market, contains a new source of protein (such as goat's milk protein) or has undergone other major changes that could impact the safety or nutritional adequacy of the formula.
If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for formula based on intact/non-hydrolysed milk protein, do you support the recommendation that the minimum protein level which requires clinical evaluation is placed in the footnote, rather than in the table? See above

☐ Yes	☒ No

Vitamin K

Vitamin K

The Chairs propose that the following drafting of vitamin K requirements for follow-up formula for older infants is recommended for adoption by the Committee:

Vitamin K

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	4	-	27
mg/100 kJ	1	-	6.5

Please comment on this proposal and provide your justification:

To re-iterate Canada's comments from CP1, Canada prefers a minimum value of 4 µg/100 kcal in order to be in line with several international organizations including the US FDA, the Early Nutrition Academy (2013), the Commission Directive 2006/141/EC and ESPGHAN 2005. There is no strong scientific justification provided to deviate from the Codex Infant Formula Standard minimum of 4 µg/100 kcal. Based on the views of the majority of eWG members (17 CM, 7 C) and based on the history of safe use, Canada supports the use of 4 µg/100 kcal as a minimum level of vitamin K.

Vitamin C

Vitamin C

No eWG consensus was reached on the establishment of a minimum vitamin C value. Based on the eWG responses, please provide rationale to support your preferred value in square brackets:

Vitamin C[15)]

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	[10] [4]	-	70[16)]
mg/100 kJ	[2.5] [0.96]	-	17[16)]

[15)] expressed as ascorbic acid

[16)] This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

Minimum levels

☒ Codex IF Standard 10 mg/100 kcal 2.5 mg/100 kJ Taking a precautionary approach and aligned with the Codex Infant Formula Standard	☐ EFSA 4 mg/100 kcal 0.96 kJ/100 kcal Based on vitamin C requirement levels established by EFSA, taking into account that complementary foods are consumed from six months.

Please provide your preferred response:

Canada would like to re-iterate our rationale from CP1: Canada supports aligning with Codex IF standard, which is based on the average content in human milk (4.5-15 mg/100 kcal) and a range of reference intakes (20, 30 and 40 mg/day).This is also aligned with the IEG 2013 recommendations and rationale. The IOM's AI is 50 mg/day. Based on consumption of 500 kcal of formula per day, this AI translates into 10 mg/100 kcal. The shelf-life stability of vitamin C is of concern, especially in liquid products. Canada has noticed significant declines in vitamin C content throughout the shelf-life of some liquid products and therefore allows a significant overage of vitamin C to ensure that the content of vitamin C remains at or above label claim by the end of the declared shelf-life of the product.

Zinc

Zinc
Based on the views of the eWG and evidence provided, the Chairs propose the following drafting of zinc requirements for follow-up formula for older infants is recommended for adoption by the Committee

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	-	1.5
mg/100 kJ	0.12	-	0.36

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

Please comment on this proposal and provide your justification:

Canada agrees with the proposed minimum of 0.5 mg/100 kcal which is close to the IEG 2015 proposed minimum of 0.6 mg/100 kcal.

Although Canada would prefer a lower GUL than the proposed 1.5 mg/100 kcal because of concerns that zinc intakes will exceed ULs/NOAELs established by RASBs, we do agree that the risk of zinc toxicity (interaction with copper) at 1.5 mg/100 kcal is low based on the available evidence. Therefore we would not be strongly opposed to this level especially given the stated technical constraints in formulating within a narrow range.

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)
No consensus was reached on the need for a minimum level, as a compromise could you accept that a statement is included in the footnote stating that national authorities can establish minimum requirements for the optional addition of DHA at their discretion.

Docosahexaenoic acid[21)]

Unit	Minimum	Maximum	GUL
% fatty acids	[-] or [0.3]	-	0.5

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

☐ Yes	☒ No

When DHA is added, our strong preference would be to have a minimum level of DHA of 0.3 % total fatty acids (FA). Canada recommends the addition of both DHA and ARA to follow-on infant formula at levels similar to those of the world-wide breastmilk content means, 0.32% of total FA for DHA, and 0.47% of total FA for ARA.

The table above therefore, should indicate 0.3% as the minimum for DHA with no stated maximum. For the GUL, as the arachidonic acid (ARA) content in human milk worldwide is 0.5%, and for keeping proportions of DHA and ARA close to those found in human milk, the GUL should be set at 0.5% of total fatty acids for DHA.

We do not support the statement included in the footnote stating that national authorities can establish minimum requirements for the optional addition of DHA at their discretion. Canada would like to re-iterate our position that the content of footnote 21 should indicate that the minimum level of DHA when added should be 0.3% of total fatty acids. Establishing a minimum DHA level is important to ensure consumers who are looking for a product containing DHA obtain a reasonable amount in the formula. The same reasons that were indicated in our previous response still apply. The footnote should read:

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, **a minimum of 0.3% of total fatty acids should be added**. Arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional

authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Reasons Previously Given in April 2016
Canada evaluated the current literature to determine the minimum levels of docosahexaenoic acid (DHA) and arachidonic acid (ARA) for addition to infant formula. As human milk (HM) is considered optimal for feeding infants, the LCPUFA needs of infants can be estimated from the average percentage of DHA and ARA in HM. The worldwide mean (±SD) concentration of DHA in HM (expressed as weight percentages of total fatty acids) is 0.32% ±0.22% and that of ARA is 0.47% ±0.13% (Brenna et al., 2007). An FAO expert panel has recommended adequate intakes of LCPUFAs to be 0.2-0.36 % of total fatty acids (% FA) for DHA, and 0.4-0.6% FA for ARA (FAO 2010). The most recent data concerning Canadian human milk (HM) content of LCPUFAs (Ratnayake et al., 2014) found that the mean % FA was 0.3% (±0.2 SD) for DHA and 0.4% (±0.1 SD) for ARA in HM samples collected in 2011. Canada's current position is to allow the addition of both DHA and ARA to follow-on infant formula at levels similar to those of the world-wide means.

1. Brenna JT et al. Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr. 2007 Jun; 85 (6):1457-64.

2. Food and Agriculture Organization of the United Nation. Rome, 2010. Fats and fatty acids in human nutrition. Report of an expert consultation.

3. Ratnayake, WMN et al. Mandatory *trans* fat labelling regulations and nationwide product reformulations to reduce *trans* fatty acid content in foods contributed to lowered concentrations of *trans* fat in Canadian women's breast milk samples collected in 2009-2011. Am J of Clin Nutr 2014;100: 1036-40.

Optional Ingredients: L(+) lactic acid producing cultures

Optional addition L(+) lactic acid producing cultures		
[3.3.2.4 Only L(+) lactic acid producing cultures may be used]		
Several eWG members noted there are two purposes for the addition of L(+) lactic acid producing cultures referring to both the acidification of formula and supplementation with probiotics. Please indicate if you consider that the sub-Section 3.3.2.4 (Optional ingredients) should refer to one, or both types of addition.		
☒ Two purposes: acidification of formula **and** supplementation with probiotics	☐ For the purpose of acidification of formula **only**. Contains minimal amounts of viable bacteria.	☐ For the purpose of supplementing with probiotics **only**
Please provide justification for your preferred response: Canada supports the inclusion of the two purposes, as in 3.3.2.4 as per the Codex Standard for Infant Formula. The current situation in Canada is that certain L (+) lactic acid producing cultures which have undergone a clinical safety assessment are permitted for addition to infant formula as sources of probiotics. Canada recognizes that L (+) lactic acid producing cultures are being added in other countries in order to acidify infant formulas.		
If you consider that standard should allow for both types of addition, please indicate if you think that this should be captured within 3.3.2.4, or as two separate clauses within the Optional Ingredients Section (Section 3.3.2).		
Captured within 3.3.2.4 is our position.		
Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.		
☒ The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence ☒ Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria ☒ For the purpose of producing acidified formulas		

☒ Non-pathogenic lactic acid cultures may be used **OR** ☐ No additional wording is required. Alignment with the Codex Infant Formula Standard
Please provide justification for your response and any proposed draft text: **Canada would like to suggest the following amended wordings:** The safety and suitability of the addition of [each] strain~~s~~ shall be demonstrated by generally accepted scientific evidence. Non-pathogenic lactic acid cultures ~~may~~ [must] be used.

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

Proposed approach

Mandatory (core) composition
Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is : • Evidence to support nutritional issues for young children of global concern; • Contribution to the overall nutritional quality/integrity of the product; • The contribution of key nutrients from cows milk for equivalence; and • The strength of committee support for including in the core composition.
Answer: Canada generally supports the approach taken for determining the mandatory (core) composition for FUF-YC. However, more work needs to be carried out on the nutritional quality and integrity of the product, since the list of mandatory (core) nutrients was extended since CP1. For instance, for mineral nutrients, calcium addition, along with iron, zinc and sodium would not result in a balanced product unless nutrients such as magnesium, phosphorous and potassium are also present or added. Equivalence to cows' milk as well as the nutritional requirements of young children should be the prime considerations for selecting nutrients and determining levels, along with provisions for the key nutrients needed by population sub-groups with nutritional deficiencies. We consider that the fourth principle is subjective. It is highly unlikely that the committee would support the inclusion of a nutrient that does not meet the first three principles. Therefore, we suggest removing the fourth principle.
Should there be a minimum number of principles that each nutrient must meet in order for it to be considered part of the mandatory (core) composition, or requiring specific compositional parameters in follow-up formula for young children? Please state what this should be.
Answer: If the eWG is in agreement to retain the fourth principle, Canada is of the opinion that having two or more principles that each nutrient meets would be the minimum number in order for it to be considered part of the mandatory (core) composition, or requiring specific compositional parameters in FUF-YC.
Voluntary Nutrient Additions *Further to the mandatory (core) composition, other essential nutrients may be added to follow-up formula for young children, either as a mandated addition to the (core) composition required by national authorities, or as a voluntary addition by manufacturers. These nutrients can be chosen from the essential composition of follow-up formula for older infants. The nutrient levels must be:* • *as per the min, max, GULs stipulated for follow-up formula for older infants; or* • *based on the min, max, GULs stipulated for follow-up formula for older infants, and amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants, or* • *in conformity with the legislation of the country in which the product is sold.* *Note: all footnotes relevant to these listed essential nutrients, also apply when added to follow-up formula for young children*

QUESTION:
Please comment on the proposed approach presented above for the voluntary addition of other essential nutrients. If you do not support this approach, please present an alternative approach with justification.

Answer:
Please provide justification for your answer:

Canada would prefer that the eWG and Committee spend more time on establishing the principles for voluntary addition of essential nutrients. This could, for instance, include ensuring that the nutrient content is appropriate for YC when used in typical amounts in the diet. If minimum and maximum amounts are provided for each nutrient, this should provide sufficient flexibility for the manufacturer to formulate the product. One of the original aims of the Committee was to support the formulation of products for free trade between countries, and too much variation in the Standard for FUF-YC will make that more difficult.

QUESTION:
Are there any essential nutrients that are not part of the proposed mandatory (core) composition, where the levels would need to be different to that for follow-up formula for older infants, noting that the principles would allow for deviating from the level stipulated for older infants if the nutrient needs of the local population and scientific justification warrants this? Please provide justification for your answer.

Answer:
Please provide justification for your answer:

Canada repeats that we believe that the Standard should be clear on the amounts of each nutrient that can be added to FUF-YC, to support free trade considerations and the nutritional integrity of products across jurisdictions. Each of the remaining nutrients should be assessed for setting the appropriate content in FUF-YC. The levels of certain nutrients may need to be different for YC than OI. If they are not to be added, a rationale should be provided.
The remaining nutrients are (from Codex Stan 72 for IF):
Vitamin E
Thiamin
Niacin
Vitamin B6
Pantothenic Acid
Folic Acid
Biotin
Phosphorus (unless it is decided that setting a Ca:P ratio is sufficient)
Magnesium
Chloride
Potassium
Manganese
Iodine
Selenium
Copper

Optional Ingredients

- In addition to the [mandatory (core)] compositional requirements [and voluntary essential nutrient provisions] listed under [insert appropriate subsection] ~~to~~ [and] [insert appropriate subsection], other ingredients or substances may be added to follow-up formula for ~~older infants~~ [young children] where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.
- When any of these ingredients or substances is added, the formula shall contain sufficient amounts to achieve the intended effect, [taking into account levels in human milk].
- [The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added]. The Chairs propose deleting the third bullet point in preference for a principles based approach rather than inclusion of any substances in a list.

QUESTION:
Please comment on the proposed approach and principles presented above for the voluntary addition of

optional ingredients and substances to follow-up formula for young children. If you do not support this approach, please present an alternative approach with justification.
Answer: Canada agrees with the proposed approach for optional ingredients.
QUESTION: Please comment on whether the second principle (bullet point 2) should include the requirement that levels of optional ingredients or substances should 'take into account levels in human milk' for follow-up formula for young children. Please provide justification for your answer.
Answer: Canada supports the use of cows' milk as the reference liquid beverage in the diets of YC. *Please provide justification for your answer:* Each ingredient/nutrient should be considered for addition based on the requirements of young children and the provision of key nutrients needed by population sub-groups with nutritional deficiencies, as well as the nutrients in cows' milk. The nutrient content of human milk can also be considered, when appropriate. Therefore, the section in brackets from point 2 should read as follows: [taking into account levels in human milk, **as appropriate**].
QUESTION: Do you support deletion of the third bullet point for follow-up formula for young children?
Answer: Canada supports deleting the third bullet point in preference for a principles-based approach rather than the inclusion of any substances in a list. *Please provide justification for your answer:* This is because optional ingredients are a developing area, scientifically and compositionally, and the list would soon be out of date, e.g. probiotics, non-digestible carbohydrates.

Energy contribution from macronutrients

Energy contribution from macronutrients
Please provide comment and justification as to whether it is necessary to define specific macronutrient percentage contribution to overall energy.
Answer: Canada is of the opinion that the minimum and maximum levels set for the macronutrients should be sufficient, especially if minimum and maximum levels are also set for the energy density.

Energy

Energy		
Members of the eWG have recommended that the energy density of follow-up formula for young children should be established, and the following levels proposed: **Energy**		
Unit	**Minimum**	**Maximum**
kcal/100 ml	[60] [45]	[70]
kJ/100 ml	[250] [188]	[293]
Should the range for the energy density of follow-up formula for young children accommodate the energy content of full fat cows' milk *and* reduced fat cows' milk, or align with the minimum energy density of follow-up formula for older infants?		
☒ FUF-older infants & full fat cows' milk 60 kcal/100ml 250 kJ/100 ml		☐ Reduced fat cows' milk (~1.5-2% fat) 45 kcal/100 ml 188 kJ/100 ml
Please provide justification for your answer Canada supports an energy density of follow-up formula for young children to accommodate the energy content of full fat cows' milk but not reduced fat cow's milk. In Canada, we do not routinely recommend reduced fat cows' milk to be used for young children aged 1 – 2 years. This is because it may compromise a young child's intake of energy and essential fats. This can adversely affect growth and		

development (Butte et al., 2004). Full fat cows' milk supports the normal growth and development of young children from 1-3 years.

Butte, N. et al., (2004). The Start Healthy feeding guidelines for infants and toddlers. The American Dietetic Association,104(3): 442-454.

Do you support establishing a maximum energy density for follow-up formula for young children? If so, do you have suggestions as to how this level should be derived?

Answer:

Yes. The maximum energy density can be partly derived from the maximum product specification requirements that the manufacturer will need in order to support the label claim amount. It should in any case be no higher than the maximum amount in breast milk. (Table 24 only provides the **average** energy content of breast milk at 70 kcal/100 mL).

Protein

Protein

Considering the eWG's varied views, are minimum and maximum requirements necessary?
If so, please state your preferred approach on how to establish protein requirements?

Please provide justification for your answer

Canada continues to support the inclusion of particular compositional requirements; minimum and maximum for protein in the Standard for FUF-YC consistent with levels typically found in cows' milk, and taking into consideration the nutritional requirements of young children aged 12-36 months.

Should there be requirements for protein quality? If so how this might be achieved? Please consider both the current Follow-up formula standard, and proposals within the draft standard for older infants.

Yes, Canada suggests including requirements for protein quality in order to meet the requirements of each essential and semi-essential amino acid, and to avoid the use of poor quality protein, especially in countries with limited resources.

Please provide justification for your answer

It is Canada's position that protein quality and methods to assess protein quality are equally important to the establishment of protein requirements and should be further discussed and assessed by experts in the field.

Canada would like to note that the FAO Expert Committee, in its report "Dietary protein quality evaluation in human nutrition" (2013) recommends using a new protein quality method, i.e. digestible indispensable amino acid score (DIAAS) instead of Protein Digestibility Corrected Amino Acid Score (PDCAAS) while evaluating dietary protein quality. However, in their 2014 report "Research approaches and methods for evaluating the protein quality of human foods", the FAO working group notes that "… the complete value of DIAAS could not be realized until there are sufficient accumulated digestibility data for human foods as determined by competent national and or international authorities…." Before a final decision is made concerning the adoption of DIAAS, there will be a need to review the practical effects for public health policies and programs in using true ileal amino acid digestibility (via DIAAS) instead of fecal crude protein digestibility (via PDCAAS).

While methods such as PDCAAS or DIAAS could be used to evaluate the dietary protein quality of a FUF, this should not be used as the only way to evaluate the protein quality of a new FUF product. These methods, rather, could be used as the target quality measurement for formulations which would be tested in a clinical setting.

Canada continues to use Protein Efficiency Ratio (PER) rat bioassay for assessing the quality of protein for new infant formulas and as part of the method to determine eligibility for protein content claims and for several types of substitute foods. The PER has advantages because it allows for detection of anti-nutrient effects that affect growth since it is conducted in growing animals.

Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
☐ Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	☒ Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
☐ Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	☐ Alternative value, please specify
Please provide justification for your answer Please see response provided below.	
Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?	
☒ Proposed FUF-older infants & cows' milk 6.0 g/100 kcal 1.4 g/100 kJ	☐ Alternative value, please specify
Please provide justification for your answer A minimum total fat content of 4.4 g/100 kcal and a maximum total fat content of 6.0 g/100 kcal aligns with several recent international recommendations such as the IEG (2013 and 2015) and the Report from the Commission to the European Parliament and the Council on Young-Child Formulae (March 2016). This is also similar to recent recommendations outlined in EFSA 2014 for total fat content in FUF-YC: 4.0 to 6 g/100 kcal, which would provide about 35 E% - 55 E% (similar to that in breast milk (6.1 g/100 kcal and whole cow's milk (5.5 g/100 kcal)).	

Essential Fatty acids

Lipids	
Based on the eWG recommendation to give consideration to the fatty acid profile of follow-up formula for young children, including maximum levels for trans fat, and noting the levels in full fat and reduced fat cows' milk, please state your preferred levels (with justification) as below: Should levels for linoleic acid, α-linolenic acid and phospholipids be established for follow-up formula for young children? Please stipulate what these levels should be; min, max, GUL.	
Please provide justification for your answers. Canada's position is YES, levels for linoleic acid, α-linolenic acid and phospholipids should be established for follow-up formula for young children. We would like align with the level proposed by IEG (2015) for linoleic acid (LA) of 500 mg/100 kcal (72 mg/100 kJ). Canada supports the adoption of the proposed CODEX FUF-OI guidance upper level (GUL) for LA of 1400 mg/100 kcal (335 mg/100 kJ). For α-linolenic acid (ALA), the IEG (2015) and Proposed CODEX FUL-OI minimum level of 50 mg/100 kcal (12 mg/100 kJ) with no maximum specified, is also the position that Canada holds as we agree that these levels are considered adequate for the majority of infants/young children. Regarding phospholipids, Canada agrees with setting the same maximum phospholipid level of 300 mg/100 kcal (approximately 2 g/L) as for FUF-OI based on the precautionary approach, which is in alignment with IEG (2013) and EFSA (2014).	
Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?	
☒ Yes	☐ No

Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG?
☒ Yes
☐ No
☐ Alternative, please specify and provide justification for your answer.

Justification for Yes:
Canada agrees with aligning with the Codex IF Standard and the proposed Standard for Follow-up for Older Infants as the European Union (2006), ESPGHAN co-ordinated International Expert Group (2005), and FSANZ Std. 2.9.1, all have guidelines that the LA:ALA ratio in infant formulas should be 5 to 15:1 since LA and ALA compete for the same desaturase and elongase enzymes involved in the synthesis of long chain PUFA (LCPUFA). We believe that this range also applies to young children aged 1-3 years.

Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?

☒ Yes Should this level be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk? ☒ Yes ☐ No ☐ Alternative, please specify and provide justification for your answer.	☐ No

Justification for Yes:

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

Canada proposes that a maximum level should also be established for palmitic acid. The rationale is that the effects of palmitic acid on blood lipid profile are at least as detrimental as those of lauric acid and myristic acid, While palmitic acid raises total and LDL-cholesterol in adults (which lauric and myristic acid also do), additionally palmitic acid increases the total cholesterol/HDL-cholesterol ratio (an effect that is not observed with lauric and myristic acids) (Mensink et al 2003). The total cholesterol/HDL-cholesterol ratio is considered as a better marker of cardiovascular disease risk than total cholesterol or LDL-cholesterol. In addition, the amounts of palmitic acid in cow's milk are higher (about 22-35% of fatty acids w/w, thus expected to have a relatively high impact on blood lipid profile) than the amounts of lauric (about 2-5%) and myristic (about 8-14%) (Jensen 2002). Therefore, if maximum levels are established for lauric and myristic acids on the basis of their detrimental effect on blood lipid profile in adults, maximum levels should also be established for palmitic acid. Canada proposes that the maximum level for palmitic acid should not be higher than 35% of fat, based on average cow's milk content in Europe and North America (Jensen 2002, Soyeurt 2008, Lindmark Mansson 2008, Danish Food Composition Database, DTU Fodevareinstituttet).

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

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

3. Soyeurt H. Genetic variability of fatty acids in bovine milk, Base (Biotechnologie, Agronomie,

Société et Environnement) 2008; 12 (2). http://popups.ulg.ac.be/1780-4507/index.php?id=2416

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

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

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

Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.	
☒ Yes - Maximum of 3% Please state what the maximum level should be, and provide justification for your answer.	☐ No

Canada would like to re-iterate our position that commercially hydrogenated oils and fats should not be used. This is in agreement with IEG (2013) which noted that trans fatty acids have no known nutritional benefit, but may induce untoward biological effects. The trans fatty acid content of FUF should not exceed 3% of the total fatty acids, which allows for the use of reasonable amounts of milk as a source of fat from cows and other ruminant animals in FUF. This 3% is in agreement with EFSA (2014), which states that this specification is adequate.

Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (*Commercially hydrogenated oils and fats shall not be used in follow-up formula*) also apply to follow-up formula for young children?

Please provide justification for your answer.

Canada says "Yes". Please see answer above. Commercially hydrogenated oils and fats have no nutritional benefit, they have shown to be harmful, and alternatives are available.

Carbohydrates

Total Available Carbohydrates

Is a minimum available carbohydrate level required, if a consensus is reached on establishing minimum and maximum levels for energy, protein and total fat?

☒ Yes	☐ No

Please provide your rationale:

Canada agrees that if a consensus is reached on establishing minimum and maximum levels for energy, protein and total fat, a minimum level for carbohydrate should be required to maintain proper macronutrient distribution.

If you support establishing a minimum available carbohydrates level, what level do you support?

☒ Full fat cows' milk 7.5 mg/100 kcal 1.8 mg/100 kJ	☐ IEG 2015 and proposed Codex FUF-OI 9.0 mg/100 kcal 2.2 mg/100 kJ

Please provide your rationale:

NOTE: Canada notes that these figures should be in g/100 kcal or g/100 kJ.

Canada proposes 7.5 g/100 kcal as the minimum available carbohydrate level as this is consistent with the minimum typically found in cow's milk.

If limits are established for sugars, is there a need to also set a maximum/GUL for total available carbohydrates?	
☒ Yes	☐ No
Please provide your rationale: A maximum total carbohydrate limit should be set for total available carbohydrates to account for all carbohydrate sources in the FUF-YC, eg., lactose, glucose polymers, rice starch, non-digestible carbohydrates.	
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?	
☒ Yes, a maximum level should be established	☐ Yes, a GUL level should be established
Please provide your rationale: A maximum limit for total available carbohydrates should be established as the IOM sets an acceptable macronutrient distribution range for carbohydrates for children 1-3 years of age.	
If you support establishing a maximum/GUL, do you support 14 mg/100 kcal (3.3 mg/100 kJ)?	
☒ Yes	☐ No (please specify your alternative).
Please provide your rationale: **NOTE: Canada notes that these figures should be in g/100 kcal or g/100 kJ.** Canada agrees with this maximum level of 14 g/100 kcal (56% of total energy) as this level falls within the 45-65% range of total calories that the IOM has set as an acceptable macronutrient distribution range (AMDR) for carbohydrates. EFSA (2013) notes a range of 45-60% of total energy as an adequate carbohydrate range for the majority of young children aged 12-36 months, the proposed maximum falls within this range as well.	

Carbohydrates footnote		
Free sugars While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.		
☒ Proposed Codex FUF-OI Standard Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.	☐ IEG 2015 Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	☐ An alternative level (please specify)
Please provide your rationale: Canada supports the limited use of free sugars, unless the product is a food for special dietary use eg., a lactose-free or amino acid based product, when these may be needed as a carbohydrate source. The IEG states that there is no need to add sugars other than lactose for nutritional reasons. In Canada, corn syrup, corn syrup solids or sucrose are used in soy-based IF for use from 6 months plus.		
Lactose		
☒ Proposed Codex FUF-OI Standard and Codex IF Standard Lactose and glucose polymers should be the preferred carbohydrates in formula based on	☐ IEG 2015 The main source of carbohydrates should be lactose, which should provide not less than 50% of total	

cows' milk protein and hydrolysed protein.	carbohydrates, equivalent to 4.5 g/100 kcal.

Please provide your rationale:

Canada supports lactose and glucose polymers as the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Lactose is the predominant carbohydrate found in cows' milk. Glucose polymers may supplement the lactose in cows' milk to provide an adequate amount of carbohydrates.

Other permitted carbohydrates

☐ Proposed Codex FUF-OI Standard	☒ IEG 2015	☐ Something else (please specify)
Only precooked and/or gelatinised starches gluten-free by nature may be added. (NB Glucose polymers are preferred carbohydrates along with lactose).	Oligosaccharides, glucose polymers, maltodextrin and pre-cooked or gelatinised starches can be added to provide energy. Non-digestible carbohydrates and fibres that proven to be safe and suitable for the age group may be added.	

Please provide your rationale:

Canada supports the IEG (2015) list of proposed carbohydrates. This listing includes the carbohydrate maltodextrin which has been used in soy-based IF and FUF in Canada and may be used in the composition of FUF for older children. The IEG (2015) list also includes non-digestible fibres. EFSA (2013) notes that 10g/day of dietary fibre is considered adequate for the majority of children between 12-36 months of age.

Iron

Iron

While a consensus was reached on the minimum compositional requirements for iron in follow-up formula for young children, there were differing opinions on a maximum or GUL.

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.0	[2.0]	[3.0]
mg/100 kJ	[0.25]	[0.3] this should be [0.5]	[0.7]

Should a maximum level or GUL be established for iron?

☒ Yes, a maximum level should be established ☐ Yes, a GUL level should be established	☐ No

Please provide your rationale:

Canada considers that there is sufficient information to set a maximum level. The EFSA (2014) reported that there is a history of safe use and no adverse reports with its permitted maximum of 2 mg iron/day, though no studies have been designed to evaluate the health consequences of consumption of formulae containing maximum values of micronutrients.

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

If you support establishing a maximum or GUL, please select your preferred value, providing scientific rationale to support your preferred choice.

☒ Maximum (Proposed Codex FUF-OI) 2.0 mg/100 kcal 0.5 mg/100 kJ	☐ GUL (IEG 2015) 3.0 mg/100 kcal 0.7 mg/100 kJ

☐ Alternative value (please provide level (max/GUL))	

Please provide your rationale:

Canada recommends that a maximum level be established at 2.0 mg/ 100 kcal and notes that this level includes overage. A level of 2.0 mg/100 kcal is aligned to the level in follow-up formula for older infants. A maximum level of 2.0 mg/100 kcal - including overage - would balance the need of countries with majorities of iron-replete young children (but needing to prevent the development of iron deficiency (ID) and iron deficiency anemia (IDA) in some subsets of the population) with the need to prevent excess intake of iron.

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?

☒ Yes	☐ No

Please provide your rationale:

Soy protein isolates used in FUF contain phytic acid (myoinositol hexaphosphate [IP6] and other inositol phosphates), which is an inhibitor of iron absorption (Hurrell et al. 1992).To compensate for the reduced bioavailability of iron in this type of formula, separate maximum and minimum levels are required.

Hurrell et al. **Soy protein, phytate, and iron absorption in humans**. Am J Clin Nutr. 1992 Sep;56(3):573-8.

If you support establishing separate minimum and maximum/GUL levels for soy protein isolate formulae, should it be the same as the proposed Codex Standard for Follow-up Formula for older infants (a minimum of 1.5 mg/100 kcal (0.36 mg/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ)?

☒ Yes	☐ No (please provide alternative values, with justification for your response)

Please provide your rationale:

The reduced bioavailability of iron in soy protein formula, due to its phytic acid content, is the reason for the current proposal of a 50% higher iron level in follow-on formulae based on soy protein compared to the iron level based on cow's milk protein (EFSA, 2014).Therefore it is proposed that the minimum iron fortification level in soy protein-based follow-on formula be 1.5 times higher than that in cows' milk protein-based formulae. The maximum level of 2.5 mg/100 kcal, including overage, is reasonable based on the need of countries with majorities of iron-replete young children to balance prevention of ID and IDA with the need to prevent excess intake of iron.

Calcium

Calcium

No consensus was reached on the requirements for calcium in follow-up formula for young children. Noting that full fat cows' milk contributes 190 mg calcium/100 kcal (range 184 - 201 mg/100 kcal) and the average amount of calcium in reduced fat cows' milk is 259 mg/100 kcal (range 240 – 280 mg/100 kcal), Please provide comment on the below options:

Calcium Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal mg/100 kJ	[50] [90] [200] [18] [22] [24] [48]	[N.S.]	[180] [NS] [43]

Minimum:

☐ Current Codex FUF standard 90 mg/100 kcal 22 mg/100 kJ	☐ Proposed Codex FUF standard for older infants 50 mg/100 kcal 12 mg/100 kJ
☒ IEG 2015 200 mg/100 kcal	☐ Alternative value, please specify

Please provide justification for your answers. It has been recommended by the IEG (2015), that FUF for young children 12-36 months contain a minimum level of 200 mg/100 kcal. This amount is similar to the average calcium content in whole cow's milk (190 mg). Fortification at this level would help young children meet their calcium requirements, which is 700mg/day (IOM, 2011), or 600 mg/day (EFSA, 2013).

Maximum/GUL:	
☐ Current Codex FUF standard Maximum: N.S.	☐ Proposed Codex FUF standard for older infants GUL: 180 mg/100 kcal GUL: 43 mg/ 100 kJ
☐ IEG 2015 GUL: N.S.	☒ Alternative value, please specify Canada proposes a GUL of 270 mg. This value provides a 30% overage from the proposed minimum calcium amount of 200 mg and would provide a daily amount of calcium well below the UL of 2500 mg per day. This overage is a common industry practice.

Calcium	
Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included? Ratio calcium/phosphorus **Min** 1:1 **Max** 2:1	
☒ Yes	☐ No
Please provide your rationale: The mandatory addition of calcium to a product should require the inclusion of phosphorus as well, to help ensure proper mineral balance. **Is it intended to also set a minimum or maximum/GUL for phosphorus, or rely on the inclusion of this ratio?**	

Vitamin A

Vitamin A			
No consensus was reached on the establishment of a minimum or maximum vitamin A value. Please provide scientific rationale to support your preferred value: Vitamin A [x)]			
Unit	Minimum	Maximum	GUL
µg RE/100 kcal	[75] [60] [50]	[225] [180]	[200] [180]
µg RE/100 kJ	[18] [14] [12]	[54] [43]	[48] [43]
[x)] expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.			
Minimum			
☒ Current Codex FUF Std & proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	☒ IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	☐ WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ	

Please provide your rationale:

Canada could support either 75mcg or 60 mcg/100 kcal as a minimum – please see rationales for each below.

75 mcg/100 Kcal:
Canada supports 75 mcg/100 kcal. If being used as an alternative to cows' milk, this level of addition would be in upper limit in the range for vitamin A in whole cow's milk (48-75 mcg/100 kcal). Even though this level is on the upper limit of the vitamin A range in whole cow's milk, this level would be close to vitamin breast milk content, i.e., 85 mcg RE/100 kcal. Although vitamin A deficiency is rare in Canada, vitamin A deficiency is a major problem in developing countries, which further supports a higher minimum vitamin A value (IOM, 2001).

Assuming a daily intake of 500 ml of this product and an energy density level of ~60 kcal/100 ml, daily caloric intake would be ~300 kcal. This proposed minimum of 75 mcg /100 kcal would result in vitamin A intake of 225 mcg / day. (The IOM EAR is 210 mcg/day and RDA is 300 mcg/day, for young children 1 – 3 years of age)

60 mcg/100 kcal:
Canada supports 60 mcg/100 kcal. If being used as an alternative to cows' milk, this level of addition is equal to the average amount of vitamin A in whole cow's milk (i.e. 60 mcg/100 kcal).

Also, more eWG members voted for a minimum of 60 mcg/100 kcal than for a higher minimum of 75 mcg/100 kcal (6 voted for 60 mcg/100 kcal; 3 voted for 75 mcg/100 kcal). The rationale provided indicates that this level is in line with Codex IF standard and also the IEG recommendation which is based on "very high prevalence of vitamin A insufficiency globally". 4 eWG members voted for a lesser minimum of 50 mcg/100 kcal.

11 of the 14 eWG members who specified a minimum level supported establishing a vitamin A minimum lower than the proposed minimum for older infants (75 mcg/100 kcal) with levels ranging from 50-67 mcg/100kcal.

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

Maximum

☐ Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	☒ Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ

Please provide your rationale:

Canada supports a maximum of 180 µg RE/100 kcal, which is in line with the levels in the Codex IF standard and the guidance upper levels (GULs) suggested by the IEG 2015.

The IOM UL for vitamin A for young children 1 – 3 years of age has been set at 600 mcg/ day. Assuming a daily intake of 500 ml of this product and an energy density level of ~60 kcal/100 ml, exposure data indicates that a maximum of 180 mcg RE/100 kcal is below the IOM UL for young children 1 – 3 years of age (i.e., calculated vitamin A intake of 540 mcg RE/100 kcal). The current maximum level of vitamin A in the Codex FUF standard (i.e. 225 µg RE/100 kcal) is too high and calculated daily intakes would exceed the IOM UL for young children. Also, the WHO/FAO GUL is high at 200 mcg RE/100kcal. Intakes that are high may cause adverse effects in this age group.

Canada supports a maximum level for vitamin A, rather than a GUL, considering that the risk of adverse effects increases as intake exceeds the UL.

IEG (2015) notes that the proposed maximum levels of nutrients (including vitamin A) in FUF-YC (12-36 months) are derived from scientific evidence on nutritional requirements and safety in young children.

1. IEG (2015). Composition of Follow-Up Formula for Young Children Aged 12-36 Months: Recommendations of an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Ann Nutr Metab. 2015;67(2):119-32.
2. IOM (2001). Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Pp 144-145

GUL	
☐ WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ	☐ IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ
Please provide your rationale: Canada supports a **maximum** level for vitamin A, rather than a GUL.	
Do you support the footnote below, agreed to by the Committee for follow-up formula for older infants (REP16/NFSDUE Appendix III)? x) expressed as retinol equivalents (RE). 1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.	
☒ Yes	☐ No

Vitamin D

Vitamin D	
Do you support that mandatory addition of vitamin D to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: Canada supports mandatory addition of vitamin D and proposes a vitamin D minimum level of 1 µg /100 kcal which is in line with the levels in the Codex IF standard and the current minimum level of vitamin D in the Codex FUF standard. Przyrembel and Agostoni (2013) noted that complementary feeding regimens differ in countries and are determined by tradition, empirical behaviors and availability of foods. Although they stated that FUF is not needed in the diet of young children based on available evidence, they propose that if such a product were available, the vitamin D content should have a minimum of between 1 and 1.3 mcg /100 kcal which is in line with Canada's proposed levels. It is mandatory to fortify cows' milk in Canada since very few foods contain this nutrient, and sunlight exposure may be limited in some population sub-groups. Since cows' milk is fortified with vitamin D in Canada, rates of insufficiency and deficiency are low. However, vitamin D insufficiency is prevalent among young children in different parts of the world, as noted in the current consultation paper (pg. 63).	
Please state whether vitamin D should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: Canada proposes a vitamin D maximum of 3 µg /100 kcal, which is in line with the recommended maximum levels for vitamin D made by the Scientific Committee on Food and the European Commission for follow-up formulas and is the current maximum level of vitamin D in the Codex FUF standard. Canada supports a maximum level for vitamin D, rather than a GUL, considering that the risk of adverse	

effects increases as intake exceeds the UL. GULs are for nutrients without sufficient information for a science-based risk assessment.

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

1. IEG (2015). Composition of Follow-Up Formula for Young Children Aged 12-36 Months: Recommendations of an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Ann Nutr Metab. 2015;67(2):119-32.
2. IOM (2011). Dietary Reference Intakes for Calcium and Vitamin D.

Zinc

Zinc	
Do you support that mandatory addition of zinc to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: As stated in the CP2, zinc deficiency is a major problem in many countries, and Canada would be in favour of mandatory addition of zinc to FUF-YC. The minimum of 0.5 mg/100 kcal for FUF-OI is close to the proposed minimum by the IEG (2015) of 0.6 mg/100 kcal. However, Canada would not be opposed to the IEG minimum.	
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: There should be a GUL established to mitigate the risk of zinc toxicity, given the narrow range between the EAR and UL. Canada suggests the same minimum and GUL for FUF-YC as adopted for FUF-OI. We would prefer a lower GUL of 1.5 mg/100 kcal than that proposed by the IEG (i.e., 1.8 mg/100 kcal), again because of the risk of exceeding ULs and the potential increased risk of zinc toxicity when this product is consumed with zinc containing complementary foods.	

Vitamin C

Vitamin C	
Do you support that mandatory addition of vitamin C to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: Canada agrees with mandatory addition of vitamin C given that iron is on the list of mandatory nutrients, and that vitamin C can increase the absorption of non-heme iron. We support the levels established in IEG 2015, namely a minimum of 4.5 mg/100 kcal, and a GUL of 22.5 mg/100 kcal.	
Please state whether vitamin C should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: Please see answer above.	

Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: Canada supports that the nutrient content of FUF-YC should be partly based, as one of the core principles, on equivalence to the composition of cows' milk. Therefore, Canada supports the mandatory addition of vitamin B12 to FUF-YC. We propose a minimum level of 0.8 µg/100 kcal which is in line with the average vitamin B12 content of cows' milk. Assuming a daily intake of 500 mL of this product and an energy density level of approximately 60 kcal/100 mL, the proposed minimum addition level of 0.8 µg/100 kcal would result in an approximate intake of 2.4 µg vitamin B12/day, which is above the IOM's RDA of 0.9 µg vitamin B12/day for young children 1-3 years of age. 1. IOM (1998). DRIs for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin and Choline.	
Please state whether vitamin B12 should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Answer: Canada proposes a GUL of 1.5 µg/100 kcal for vitamin B12, which is in line with the proposed Codex Standard for FUF-OI. This is just above the upper bound of the range of cow's milk content of vitamin B12 at 1.4 µg /100 kcal. Assuming a daily intake of 500 mL of this product and an energy density level of approximately 60 kcal/100 mL, the proposed maximum addition level of 1.5 µg/100 kcal would result in an approximate intake of 4.5 µg vitamin B12/day. Canada supports a GUL for vitamin B12, rather than a maximum level, considering that no UL has been set by the IOM for vitamin B12 in YC aged 1-3 years. 1. IOM (1998). DRIs for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin and Choline.	

Riboflavin

Riboflavin	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Answer: Canada supports a mandatory amount of riboflavin in FUF-YC and proposes a minimum level of 342 µg/100 kcal which is in line with the average amount in whole cows' milk. Assuming a daily intake of 500 mL of this product and an energy density level of approximately 60 kcal/100 mL, the proposed minimum addition level of 342 µg/100 kcal would result in an approximate intake of 1026 µg riboflavin/day, which is well above the IOM's RDA of 500 µg riboflavin/day for young	

children 1-3 years of age.

1. IOM (1998). DRIs for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin and Choline.

Please state whether riboflavin should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.

Answer:

Canada proposes a GUL of 500ug/100 kcal for riboflavin, which is consistent with the GUL of the proposed Standard for FUF-OI, and which is in line with the upper bound of the range of riboflavin content of full fat cows' milk. Assuming a daily intake of 500 mL of this product and an energy density level of 60 kcal/100 mL, the proposed maximum addition level of 500 µg/100 kcal would result in an intake of 1500 µg riboflavin/day.

Canada supports a GUL for riboflavin, rather than a maximum level, considering that no UL has been set by the IOM for riboflavin.

1. IOM (1998). DRIs for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin and Choline.

Sodium

Sodium	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
☒ Yes	☐ No

Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.

Answer:

Canada does not support establishing a minimum level for sodium in FUF-YC. Given the ubiquitous presence of sodium in food, children aged 1-3 years will likely obtain more than enough sodium to meet their nutritional needs from the complementary foods that they eat. Therefore, Canada is of the opinion that it is more important to establish a maximum level for sodium in FUF-YC than a minimum level.

Please state whether sodium should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.

Answer:

Canada proposes a maximum level of 75 mg/100 kcal for sodium, which is in line with the IEG 2015, and also with the sodium content of full fat cows' milk (range of 64-72 mg/100 kcal).

Canada supports a maximum level for sodium, rather than a GUL, considering that the IOM has set a UL for sodium of 1500mg sodium/day for young children 1-3 years of age. Assuming a daily intake of 500 mL of this product and an energy density level of approximately 60 kcal/100 mL, the proposed maximum addition level of 75 mg/100 kcal would result in an approximate intake of 225 mg sodium/day, which is acceptable as it is well below the IOM's UL of 1500 mg sodium/day for young children 1-3 years of age.

1. IEG (2015). Composition of Follow-Up Formula for Young Children Aged 12-36 Months: Recommendations of an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy. Ann Nutr Metab. 2015;67(2):119-32.
2. IOM (2005). DRIs for Water, Potassium, Sodium, Chloride, and Sulfate.

SCOPE & LABELLING

Scope & Labelling
When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.

Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?

Please provide justification for your answer.

Canada does not consider that any of the current sections could be adopted as they currently appear due to the potential different nutritional composition of the products and indications for use etc.

Are there any labelling areas where different provisions may be required for the two age groups?

Please provide justification for your answer.

Canada proposes that the eWG should consider having two Sections for FUF-OI and FUF-YC , similar to Section A and Section B in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981 Rev 2007). This might provide clarity for each product, considering the different compositional requirements and different role of follow up formula in the diet of older infants compared to that of young children.

Labelling areas where different provisions may be required for the two age groups:

Name of the Food:

- The FUF-OI and FUF-YC should have different names considering that there is general agreement that there should be a recognized point of differentiation at 12 months for FUF, due to the different nutritional requirements and the different role of FUF in the diet of older infants compared to that of young children.

Information for Utilization/Use

- Information such as product “indication for use” to differentiate FUF products that are meant for older infants (i.e. 6 to 12 month old) from FUF meant for younger children (i.e. 12 to 36 months).
- Labelling should avoid any risk of confusion between FUF-OI and FUF-YC.

Are you aware of further issues and/or evidence that need to be considered to inform the review of the scope and labelling section of the Codex Standard for Follow-up Formula? Please state the specific provisions within the Scope or Labelling section which would be informed by your response.

Answer:

Canada requests that these aspects be considered:

Declaration of Nutritive Value
Canada notes that in the Codex Standard 72 for IF and the current Codex Standard 156 for FUF, the standards outline the nutrition information to be included and the order in which energy and nutrients are listed. We propose that the Committee consider this section since it may be divided according to FUF-OI and FUF-YC.

List of ingredients

- Similar to Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981 Rev 2007); Canada recommends adding “The specific name for ingredients of animal or plant origin and for food additives must be given. Class names may also be included for these ingredients and additives.”

Information for Utilization/Use

Canada proposes the inclusion of reference to “The Code of Hygienic Practice for Powdered

Formulae for infants and Young Children" (CAC/RCP 66-2008) in both FUF-OI and FUF-YC, as referenced in the current Codex Standard for FUF (CODEX STAN 156-1987).

Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up Formula, and if so, how and where? For example in the Scope and Labelling sections.

Answer:

Canada would support the addition of a sentence making reference to WHA resolutions and other relevant documents in the Scope of this Standard – "*The application of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the WHO Global Strategy for Infant and Young Child Feeding and relevant World Health Assembly resolutions".* This would be in line with the wording of the scope in the Codex Standard for Infant Formula (CODEX STAN 72 – 1981, Revision 2007). Canada endorsed the WHO technical guidance document on ending the inappropriate promotion of foods for infants and young children at the 69th session of the WHA.

Please comment on how CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF./7 Rev 1) for 'Ending inappropriate promotion of foods for infants and young children' and the associated technical guidance document. Please be specific in your response and comment on what aspects of the resolution or guidance should be captured within the Standard for Follow-up Formula and within what subsection it should be reflected.

Answer:

The Committee should give consideration to the Resolution and the Technical guidance document by incorporating certain recommendations into the labelling section of the Standard as follows:

Recommendations from the WHO Technical Guidance

The Committee may consider revising the definitions section of the Standard to include a footnote referencing the WHO technical guidance for "marketing", "promotion" and "cross-promotion".

Canada would suggest capturing Recommendation 4 of the WHO technical document in the Standard:

> *"**Recommendation 4:** The messages used to promote foods for infants and young children should support optimal feeding and inappropriate messages should not be included. Messages about commercial products are conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Irrespective of the form, messages should always:*
>
> *• include a statement on the importance of continued breastfeeding for up to two years or beyond*
>
> *• include the appropriate age of introduction of the food (this must not be less than 6 months);*
>
> *• be easily understood by parents and other caregivers, with all required label information being visible and legible.*
>
> *• …"*

As mentioned earlier, Canada suggests the inclusion of a provision highlighting that any messaging about these products should support optimal feeding of infants and young children and support the continuation of breastfeeding up to 2 years and beyond.

This would also be in line with paragraph PP3bis of the respective resolution (A69/A/CONF./7 Rev 1)–

> *"**(PP3bis)** Reaffirming the need to promote exclusive breastfeeding practices in the first 6 months of life, and the continuation of breastfeeding up to 2 years and beyond, and recognizing the need to promote optimal complementary feeding practices for children from ages 6-36 months based on WHO's and FAO's dietary guidelines[1] and in accordance with national dietary guidelines;"*

1 – PAHO and WHO. Guiding principles for complementary feeding of the breastfed child, 2003; WHO. Guiding principles for feeding non breast-fed children 6-24 months of age, 2005

The proposed provision could be included in Section 9.5 (Information for Utilization) of the Standard.

Canada would support further consideration on the inclusion of a provision restricting cross-promotion of breast-milk/milk substitutes in the Codex Standard for FUF-YC. This directly aligns with Recommendation 5 of the WHO technical guidance document and would fit appropriately in Section 9.6 (Additional Requirements) –

> ***Recommendation 5.*** *There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children.*
>
> *• The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).*
>
> *• Companies that market breast-milk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).*

As mentioned earlier, the definition of 'cross-promotion' can be referenced to in Section 2.1 (Definitions) via a footnote.

Taking into consideration relevant WHA resolutions and accompanying documents (section 6) and the role of product in the diet, are changes required to the current drafting of Section 9.6 of the current follow-up formula standard? Please consider both follow-up formula for older infants and for young children when answering this question and comment on whether there would may need to be different approaches for the different product categories.

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

Answer:

Yes, Canada would suggest changes to the current drafting of Section 9.6.

The Codex Standard doesn't currently recognize follow-up formula as a breast-milk substitute. The WHO technical guidance does however acknowledge that this category of products is being marketed/sold as such in certain countries. Given that there is an overlap between infant formula and FUF-OI (6-12 months), it may be beneficial to include a sentence in the Standard clarifying that FUF-OI that functions as a breast-milk substitute would also fall within the scope of this Standard. Canada is of the opinion that FUF-YC is not a breastmilk substitute. A statement to this effect should be noted in the scope.

Similar to what has been done in the Codex Standard for Infant Formula, we would like to see a list of more extensive requirements in Section 9.6 in this Standard, which reflects the provisions of the WHO Technical Guidance (e.g. Recommendation 4) as well as the provisions within the International Code of Marketing of Breast-milk substitutes (Article 9). Specific requirements could be outlined for FUF-OI and FUF-YC and then separate provisions made for each. Examples of the former would include reference to the labelling provisions outlined in the WHO's International Code of Marketing of Breast-milk Substitutes (e.g. breastfeeding should not be discouraged in any of the labelling messages of FUF-OI and FUF-YC).

Canada recognizes the need for infant formulas for special medical purposes to carry indications of use (e.g. “Hypoallergenic Formula”) and allows these statements on labels. These types of claims should be considered for FUF-OI and FUF-YC when appropriate to the nutritional composition.

Areas with which the requirements could be different between FUF-OI and FUF-YC would include nutrition labelling, indication of use and marketing/promotion requirements. For example, the nutrition labelling requirements for FUF-OI could be aligned with those of infant formula (as per the Codex Standard for Infant Formula), whereas those for FUF-YC could be more aligned with that of cows’ milk.

With respect to marketing/promotion provisions, the recommendations in the WHO technical guidance, the WHO set of recommendations on the marketing of foods and non-alcoholic beverages to children as well as the International Code of Marketing of Breast-Milk Substitutes should apply to both FUF-OI and FUF-YC. Areas where requirements could differ is in the way the products are promoted. For example, FUF-OI should not be marketed/promoted as a cows’ milk substitute whereas FUF-YC should not be marketed/promoted as a breast-milk substitute. See earlier comments for cross-promotion for FUF-YC.

Canada supports the Committee in considering including a label statement regarding the lack of necessity of FUF-YC, in this Section.