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: __The United States of America_____

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:
The United States continues to support its previous position in maintaining the minimum level of 1.8 g/100 kcals. We note that the Codex IF standard is intended to provide sufficient protein intake for infants throughout the first year of life. This FUF standard for 6-12 month older infants will be applied to products used throughout the world in circumstances where there may not be adequate protein to meet nutritional requirements during this critical period of growth and development. Therefore, we support maintaining 1.8 g/100 kcal.

We note that the protein content of breast milk declines after 6 months and the amount of protein in many first complementary foods as well as the total amount of nutrients provided by these foods appears to low to meet protein requirements for this age group [1, 2].

The US also considers protein quality to be as important as the protein quantity and supports evaluation of the protein quality for this Standard to ensure that all essential amino acids are present in amounts associated with normal physical growth and development. We note that this product, although not currently identified as a breast milk substitute, may be used as a one and we considers it appropriate to use Annex 1and maintain consistency with the Codex Standard for Infant Formula (*CODEX STAN 72-1981).*

Maximum		
	☒ 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: *The United States continues to support a maximum protein level of 3.0 g/100 kcals. This level is in alignment with the Codex IF standard (CODEX STAN 72-1981) and suitable for the 6-12 month older infant. However, we note that there is no new scientific evidence that suggests that the maximum level of 3.5 g/100 kcal would result in significant adverse nutritional issues and both of these levels are below the 20% of total calories recommended from recent scientific evaluations [3]*		
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. *The United States considers protein quality to be as important as the protein quantity. We consider the amino acid pattern in human milk to be the appropriate profile for the older infant and should mirror that of breast milk. We support inserting Annex 1 for Codex Infant Formula Standard (CODEX STAN 72-1981) as previously discussed in the response to the minimum protein level.*		
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 **hydrolyzed** 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 hydrolyzed 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. *The United States agrees that it is appropriate to retain footnote 6 but does not agree that that intact protein should be used instead of non-hydrolyzed protein because doing so would be inconsistent with the wording in the Infant Formula Standard and could create unnecessary confusion in terminology.* *We consider it appropriate to retain the concept that any hydrolysed protein should be clinically tested for growth, tolerance, and adverse events, since protein hydrolysates are manufactured by different processes, resulting in products which may vary in nutritional adequacy particularly if not from cow milk protein.*		
☐ intact milk protein	☒ non-hydrolyzed milk protein	
Please provide justification for your response. *The United States suggests that the use of non-hydrolyzed protein be retain consistency with the Infant Formula Standard's 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. *The United States considers clinical evaluation of 1.65-1.8 g protein/100 kcal necessary since there is very limited data available for such products.*
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 Table 5 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** mcg/100 kcal 4 - 27 mcg/100 kJ 1 - 6.5
Please comment on this proposal and provide your justification: *We note a typographical error in the table above regarding the units –it states mg when it should be mcg.* *The United States supports the recommendation from the chairs for the level of 4 micrograms and is not aware of any new evidence that would support lowering the level of Vitamin K.* *We note that the Codex IF standard (CODEX STAN 72-1981) is intended to provide sufficient Vitamin K intake for infants throughout the first year of life whether they have received an intramuscular injection of vitamin K at birth or not. This FUF standard for older infants will be applied to products used throughout the world in circumstances where there may not be adequate Vitamin K to meet nutritional requirements during this critical period of growth and development. We consider that lowering the vitamin K minimum places infants at risk of a hemorrhagic episode with the associated mortality and morbidity untenable [4]. Therefore, we support aligning with Codex Infant Formula standard of 4 ug/100 kcals.*

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:
The United States finds the Codex Infant Formula Standard (CODEX STAN 72-1981) to be nutritionally appropriate throughout the first year of life. Although there is some data to indicate a lower level may be adequate for infants in developed countries, a worldwide standard should consider the needs of all populations and sources of vitamin C from other foods may not be available or adequate from the developing diversified diet and the limited intake of the older infant. If the Committee decides to lower the level of vitamin C, we should consider any potential effects on iron absorption as well as product stability.

Vitamin C is known to enhance iron absorption and lowering the amount of Vitamin C in the formulation, may decrease iron absorption. Further discussion regarding the vitamin C to iron ratio should be considered before a change in the level is made. We also note that lowering the amount of Vitamin C may decrease shelf-life stability. We note that after age 4 months, the iron reserves of the infant are reduced and the infant may become iron deficient and this situation is exacerbated if the infant's prenatal conditions didn't support adequate iron reserve. Non-heme iron absorption is enhanced by vitamin C and a molar ratio of vitamin C to iron of 2:1, respectively, supports a two fold increase of iron absorption to about 10% [5].

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).

The United States supports the Chairs suggestion to align zinc levels with the Standard for Infant Formula.

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

The United States is not aware of evidence that supports setting a minimum level of DHA, at this time. As an optional ingredient, if DHA is added, consideration should be given that it is added at a level that is associated with a scientifically supported positive physiological outcome(s) to the older infant (6-12 months).

We continue to support the information found and agreed to at CCNFSDU37 in footnote 21 regarding the relationship among DHA, ARA, and EPA. We also support the sentence regarding national authorities deviating from the above conditions as stated on page 30 of the second consultation.

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.		
	☐ 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: *United States considers it important to separate the two purposes of the addition of L(+) lactic acid producing culture 1) for physiological effects in the infants gut, and 2) as a food additive that functions as an acidity regulator.* *The first purpose takes into account the scientific evidence related to the addition of microorganisms for purported beneficial physiological effects. We agree with the Chairs that FUF standards should align with Infant Formula Standard (CODEX STAN 72-1981) in regards the addition of L(+) lactic acid producing cultures.*		
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).		
The United States suggests that to avoid confusion, the two purposes of L(+) lactic acid in the FUF standard be separated as in the Infant Formula Standard where this ingredient is listed as an optional ingredient and listed under Food Additives. Formulas that are acidified by use of L(+) lactic acid bacteria are used in production of a fermented product and the amount of bacteria that remain are not there for physiological effects, although they may have some effect.		
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: The United States considers the first three listed suggestions as relevant but we do not consider additional wording needed since the addition of any optional ingredient requires that the safety and suitability of the ingredient is covered under General Principles for establishing minimum and maximum values for essential composition of infant formula, Annex II CODEX STAN 72-1981.		

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: The United States appreciates all the work the Chairs have done in providing the eWG with scientific discussion and suggested avenues to pursue. We consider the principles identified by the chairs for the product for this age group helpful. We consider that the product for the 12-36 month old should contribute a positive nutritional profile/ composition of the complementary diet as a liquid beverage and that the product addresses the global inadequacies that have been identified. The advantage of such a product is that it can provide essential nutrients at levels not found in cows' milk and at more ideal levels.

The discussion to date, and the compositional profile discussed so far, suggests that it is a distinctly different product from FUF for older infants (FUF-OI). We have continued to use the designation FUF for young children in these comments but, as indicated in our responses to the questions on scope and labelling, we consider that a distinctly different name is needed for the accurate identification and safe use of this product category.

The product could be a cow milk alternative beverage that would be formulated to address the nutritional inadequacies that have been identified for young children throughout the world. We note that by providing the nutrient profile, plant based protein products could be included in this category as in the infant formula standard and the proposed standard for FUF-OI. In addition, the nutritional profile for the standard for the 12-36 month product should allow for the combinations of plant sources as the science and technology suggests that such proteins might be appropriate.

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: The General Principles that guided the Infant Formula Standard (Appendix II) should be used as a guide for this Standard as well. Modifications could be made if the principle isn't applicable but all should be considered.

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:

The United States agrees with the approach described above and we would support the voluntary addition of other essential nutrients so that the flexibility needed to address differing needs is addressed.

However, we note that too much flexibility could become problematic when setting a "standard" for the product for the 12-36 month old and could render such a "standard" meaningless resulting in products that could be so varied the consumer will be confused regarding appropriate use.

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:

The United States considers that the complementary diet of the young child should have all the nutrients

needed for normal physical growth and development. However, given the global inadequacies that have been identified, cow milk without modification would not provide the nutrients of concern particularly if the other complementary foods are not nutritionally adequate or in short supply. If cow milk is not available, then the complementary foods would have to make up the difference and are not likely to be able to do so, even if some foods are fortified. A cow milk alternative beverage that can bridge the nutrient gap could provide a safety net for these children.

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:
Please provide justification for your answer:
The United States supports the Chairs' proposal to delete the third bullet and supports the approach suggested for the addition of optional ingredients as principle based.

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:
Please provide justification for your answer:
The second bullet is important as it relates to the effect(s) that the ingredient is purported to support. If a certain level of an optional ingredient has been shown scientifically to have an intended effect, then that is the level that should be in the product, assuming other viable sources are not available. Adding less would be misleading the consumer into thinking the product will perform in way that it cannot.

QUESTION:
Do you support deletion of the third bullet point for follow-up formula for young children?

Answer:
Please provide justification for your answer:
As stated above, the United States agrees with the suggestion from the chairs and supports the deletion of the third bullet as the Chairs suggest and rely on principles rather than a list.

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:
The United States considers it important and necessary to define the specific macronutrient percentage contributions to overall energy in this product in order to provide an appropriate distribution of energy sources for this age group and provide for the nutritional integrity of the product.

Energy

Energy		
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 *The United States considers the period between 12 and 36 months of age a transitional period in which the complementary diet advances. Concerns about the development of obesity has resulted in the suggestion that reduced fat cows' milk may be appropriate for children in this age group when there is a family history of obesity or the child is gaining excessive weight or level of saturated fat intake is of concern. However, unless these issues have been identified, the recommendation is for full fat milk in order to meet the caloric demands of growth and development [6]. We also suggest that consideration be given to the change in the level of the other macronutrients when a change in the percent of fat is made, so that more protein and/or carbohydrate would be needed to meet total calories.* *We also consider it important that the total energy level allows for protein utilization for growth and maintenance and not as a source of energy.*		
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: *The United States considers that the product's total energy density should be within the caloric range of full fat cows' milk, as caloric densities than that of cows' milk may suggest a different use for the product.*		

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?
P*lease provide justification for your answer* *The United States appreciates the complexity and diversity of views presented by the Chairs. We consider it important to establish a minimum level for protein (and fat) in the product for 12-36 month olds since protein is needed for continued growth and development and should not be used not as a source of energy. We note that the Acceptable Macronutrient Distribution Ranges (AMDRs) for this age group for protein is 5% to 20%. We also note that the conversion of dietary protein to body proteins does not operate at 100% efficiency and dietary protein needed for growth must be adjusted to account for this inefficiency which is about 58%. [6].* *We further consider that since cow milk provides 21% of energy from protein, a protein level for this product, in light of the limitations of protein availability, inefficiency of conversion to body proteins, and protein quality, levels that could contribute 10% to 20% of energy from protein without adverse effects could be considered.*
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.
P*lease provide justification for your answer* *The United States considers it appropriate to have a protein quality requirement for FUF for young children. We consider that the protein quality for 12-36 months as important as that for the older infant and both essential and non-essential amino acids and pattern should be considered. However, the United States considers further discussion on the appropriate amino acid pattern is needed for the 12-36*

month old since the Committee agreed that 12 months of age was a the point of demarcation for the composition of the products .

We are aware of recommendations from the joint FAO Expert Consultation on Protein Quality Evaluation in Human nutrition in 2011 [7], as well as the discussion regarding the use of the amino acid pattern provided in this document for the 12-36 month old. We also note that here are considerable issues and concerns with replacing the PDCAAS with DIAAS approaches that were identified by the Working group of Experts that include limited data on true ileal amino acid digestibility in foods for humans, lack of internationally harmonized methods, and limitations of the regression model. For the purposes of this product for this age group, the statement included in 3.2.1.1 from the current FUF Standard (CODEX STAN 156-1987) "The quality of the protein shall not be less than 85%" of that of casein" could provide adequate assurance that the protein quality requirement would be met, regardless of the protein source.

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 4 g/100 kcal
Please provide justification for your answer *The United States supports discussion of the use of the minimum level in the proposed Codex standard for young children. Children ages 24 and 36 months of age consuming 30% of calories from fat appear to have adequate growth [8] but not children 12-24 months old. However, more recent research provided in the Commission directive and EFSA NDA Panel of 2014 suggests higher levels of total fat intake. Since this is a global standard, the higher level of fat may be more appropriate in less developed parts of the world where resources are limited. However, a higher minimum level of fat would reduce the protein and carbohydrate energy contributions. The United States suggest consideration be given to an energy distribution profile that would allow flexibility over the entire age group of 12-36 months so that all the macronutrients are accounted for in the distribution of energy.*	
☒ 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 *The United States supports the level in proposed FUF for older infants and cows' milk of 6.0 g/100 kcal since it also accommodates the level in cows' milk and is the level in the current FUF (CODEX STAN 156-1987) and would provide for flexibility in macronutrient composition.*	

Essential Fatty acids

Lipids
Please provide justification for your answers. *The United States supports including maximum levels for industrial trans fatty acids and considers that the addition of commercially hydrogenated fats should not be permitted. We note that the adverse effects of trans fat from commercially hydrolyzed fats were unknown when the FUF standard was originally considered but should certainly be considered now. With this new information in mind, we support inclusion of the revised Codex Standard for FUF for older infants Footnote 7 that was agreed to at CCNFSDU37.* *The United States supports the inclusion of minimum levels for linoleic and alpha linolenic acids with consideration for Maximums or GULs as appropriate for this age group that could be expressed as*

percentages of the total calorie content. The sources of these essential fatty acids in the complementary diet may not available in adequate amounts and should be considered for this product.	
Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?	
☒ Yes 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.	☐ No
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
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 Please state what the maximum level should be, and provide justification for your answer.	☐ No
Please provide justification for your answer. *The United States supports the level of trans fatty acids that shall not exceed 3% of total dietary fats as well as the rest of the information provided in footnote 8 from the Infant Formula Standard regarding trans fat content of cow milk fat, if that is a source of fat in a product.* *The United States also supports the inclusion of footnote 8 that limits lauric, myristic, and erucic acid content as well as trans fatty acids and phospholipids.*	

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: *The United States considers an approach to setting a minimum level for carbohydrate should be based on the percentage of energy left from setting the maximums for protein and fat. We suggest that the level of carbohydrate be calculated by subtraction.*	
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: *The United States notes a typographical error above. The units for carbohydrates should be grams (g) not milligrams (mg) as indicated in the box above. We consider that the carbohydrate level should provide an appropriate percentage of energy that fits the macronutrient profile after the percent provided by protein and fat is established. The percent of carbohydrate in human milk is about 40% and full fat cows' milk is about 32%. We note that that 9 g/100 kcal provides about 36% of calories from carbohydrate in 2% fat milk demonstrating that adjustments to the fat level affects the carbohydrate percentage.*	
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: *The United States considers that the carbohydrate content would be constrained by the total energy requirement and the percentage of energy provided by protein and fat. If the footnote for free sugars is accepted, then a GUL would not seem necessary since the amount of carbohydrate would be constrained by the percentages.*	
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: *See response above.*	
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: *Although the United States considers that the amount of carbohydrate would be constrained by the percentages of the other macronutrients, the minimum and maximums in the Infant Formula Standard would fit within the percentage constraints and could be considered as well once the unit correction is made (grams not milligrams).*	

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: *The United States agrees that added free sugars should be limited and not incorporated to entice the child's consumption of the product because it is sweetened. This age group is learning and acquiring taste preference and learning to prefer sweetened foods may lead to overconsumption of sweetened foods as well as dental carries [9]; however, the acquisition of taste preferences is complex [10].*	
Lactose	
	☐ IEG 2015 The main source of carbohydrates should be lactose, which should provide not less than 50% of total carbohydrates, equivalent to 4.5 g/100 kcal.
Please provide your rationale: *The United States agrees that the main source of carbohydrates should be lactose unless the product is not milk based and, for example, soy protein isolate is used. Use of soy protein isolate would not be compatible with lactose so that an alternative carbohydrate source should be included.*	
Other permitted carbohydrates	
☐ Proposed Codex FUF-OI Standard Only precooked and/or gelatinised starches gluten-free by nature may be added. (NB Glucose polymers are preferred carbohydrates along with lactose).	☒ IEG 2015 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.
☐ Something else (please specify)	
Please provide your rationale: *Although the United States considers the carbohydrates listed by the IEG as appropriate for this age group as the diversified diet would include similar sources; however, we are confused by the inclusion of non-digestible carbohydrates and fibers here and not under optional ingredients. We suggest the non-digestible carbohydrates and fibers be separated from this listing in keeping with the core composition concept.*	

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]	[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: *The United States would appreciate clarification on whether there has been a philosophical shift away from the General Principles for setting minimums and maximums in Annex II of the Infant Formula Standard. We support a maximum level being set when there is a potential for adverse/toxic effects.* *The United States is concerned with the level of iron in relationship to other trace minerals zinc and copper*			

as well as potential adverse effects from high levels of iron itself. We consider that benefits and risks enter this equation and note that in resource constrained settings the level of iron needed may be greater than in other settings to manage iron deficiency anemia prevention and treatment. Although a GUL of 3 mg/100 kcal would provide flexibility for those situations where more iron may be needed, we suggest that this GUL level be considered as a maximum. We also note that there are many public health programs that provide cereal and milk products that have been fortified with iron and national authorities need to consider the programs available to their population. We also note that there are few studies that compare functional outcomes with different levels of iron and the dietary sources to achieve optimal outcomes. [11] [12]. *Additionally, the United States suggests that the eWG consider potential nutrient interactions associated with mandatory (core) nutrients including trace minerals as described under number 5 of the General Principles (CODEX STAN 72-1981) .*
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: *The United States considers the GUL of 3 mg/100 kcal should be considered a maximum level that provides for technological feasibility as well as a level that would permit slightly higher iron content for flexibility as described above.*
Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?

☒ Yes	☐ No

Please provide your rationale *The United States considers that although the range for soy protein isolate formulae (1.5 -2.5 mg/100 kcal) would be contained in the suggested minimum and maximum for iron (1 mg and 3 mg/100 kcal, respectively), it may provide clarity to have these separated or as a footnote. It is likely that the proposed codex standard for older children which is based on the lower availability of iron due to anti-nutrient factors in soy would also be applicable to the young children.*
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 United States supports the minimum level of 1.5 mg/100 kcal (0.36 mg/100 kJ) based on the lower absorption of iron from soy protein isolate formulae. However, we would consider a maximum of 3 mg/100 kcal to allow for technical feasibility as well as flexibility, if it is accepted.*

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 mg/100 kcal mg/100 kJ	**Minimum** [50] [90] [200] [18] [22] [24] [48]	**Maximum** [N.S.]	**GUL** [180] [NS] [43]
Minimum:			
☒ Current Codex FUF standard		☐ Proposed Codex FUF standard for older infants	

90 mg/100 kcal 22 mg/100 kJ	50 mg/100 kcal 12 mg/100 kJ
☐ IEG 2015 200 mg/100 kcal	☐ Alternative value, please specify
Please provide justification for your answers. *The United States supports the mandatory inclusion of calcium in a product for young children so that bone mineralization is not compromised during this time of growth. Please refer to our discussion regarding the use of the General Principles in setting minimum and maximum levels for nutrients.* *If the product is to be used as an alternative to cow milk, a higher minimum level than that in the current or proposed Codex FUF standard should be considered. As a cow milk alternative, the calcium level in cow milk would contribute to the nutritional needs without exceeding the IOM's Recommended Dietary Allowance (RDA) for calcium of 700 mg/day for ages 12-36 months could be considered [13]. This level is similar to the EFSA recommendation of 600 mg/d. Considering that cows' milk contains about 200 mg Ca/100 kcal, the IEG recommendation should also be considered[9]. The maximum or GUL cannot be determined until the minimum is set and may not be needed if the calcium to phosphorus ratio is mandatory. We also suggest that the upper tolerable intake level of 2500 mg/d from all sources of calcium be taken into consideration when deciding on the maximum level.* *The United States notes that the addition of calcium to a product suggests that consideration for the inclusion of other minerals such as phosphorus should be assessed in order to ensure proper nutrient balance. We support the calcium to phosphorus minimum and maximum ratios because imbalance in calcium and phosphorus levels can lead to poor bone mineralization and other issues. Other potential nutrient interactions with other minerals (e.g. magnesium, zinc, and iron) and relationships would also need to be considered so that the nutrients are bioavailable to the young child from the product's matrix.*	
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
The United States supports further discussion as to an approach for setting appropriate values for calcium in the product for young children 12-36 months once consideration has been clarified as to the use of this product in the diversified diet.	

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 United States supports the calcium to phosphorus minimum and maximum ratios because imbalance in calcium and phosphorus levels can lead to poor bone mineralization and other issues.*	

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:
The United States supports mandating a vitamin A level in follow up formula for young children since deficiency of vitamin A is a major nutritional problem for this age group in developing countries. We suggest a minimum amount of 75 ug RE/100 kcals based on Current Codex FUF and proposed Codex FUF-OI standard.

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:
The United States considers that a maximum amount of 225 ug RE/100 kcal based on Codex FUF standard is an appropriate level to avoid the risk of toxicity. To be consistent with the General Principles, the potential for adverse effects argues for a maximum level.

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:
See response above on maximum levels.

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: *The United States supports the mandatory addition of vitamin D. All cow's milk in the United States is fortified with vitamin D at a level of 2.5 µg/240 mL (100 IU/240 mL). Vitamin D is required for calcium absorption and is also involved in maintaining bone mineral homeostasis as well as regulating renal calcium excretion [9].*
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: The United States considers it appropriate to have a maximum level to be consistent with the General Principles as mentioned previously. The United States suggests that consideration be given to the level of vitamin currently added to cow milk as a guide for levels in this product. United States fortifies cow milk with vitamin D at a level of 2.5 µg/240 mL (100 IU/240 mL).

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: The United States notes that zinc was identified as being inadequate in the diet and supports its addition. As we have stated previously, we consider it important to consider the relationship of the micronutrient in this product to avoid potential interactions and to be consistent with the General Principles.	
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: *The United States notes that zinc has been identified as a nutrient of global concern and supports its addition as a core nutrient. As we have previously stated, we consider it important to consider the relationship of the micronutrients in this product to avoid potential mineral:mineral interactions [11] .*	

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: *The United States considers the FUF Codex Stan 156-1987 level of 8 mg/100 kcal as a reasonable minimum to consider because this level provides the Dietary Reference Intake (DRI), assuming the consumption of 500 ml/d. Further, vitamin C facilitates iron absorption and as we've already mentioned that relationship should be considered if the level of vitamin C is lowered. Further, vitamin C is an ingredient that is sensitive to heat and oxidation and any lower minimum level should be shown to provide the for the nutritional needs of young children 12-36 months of age throughout the shelf-life of the product.*	
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: *The United States considers that although the FUF Standard does not indicate a maximum or GUL, we would consider the proposed codex FUF-OI of 70 mg/100 kcal as a GUL and well below the IOMs UL.*	

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: The United States supports consideration of vitamin B12 as mandatory and considers its addition particularly important if the product is based on plant protein sources. We note that there is considerable variability in the amount of vitamin B12 from cow milk [15]	
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: *The United States notes that there is a range of levels to consider a GUL and suggest that level take into consideration the level in cows' milk of 0.8 mcg/100 kcal and would not want levels of B12 that would require its removal from cows' milk sources.*	

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: *The United States supports consideration of riboflavin in the product because we note that its content in cows' milk is also rather variable [15]. However, we are also concerned about the levels of other vitamins that are heat labile and would support further discussion and clarification of those not included.*	
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:	

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: *The United States appreciates the discussion presented by the Chairs regarding their view that although unstated, there may be a concern that a maximum level of sodium needs to be set. Since this product is to be consumed as part of a mixed diet, perhaps consideration could be given to applying a percentage based on total calories rather than to the individual food.*	
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:	

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.

Yes, the United States considers that certain of the current labelling provisions for follow up formula can be adopted as is. However, we consider the nutritional needs of the 6-12 month older infant to be different from the 12-36 month old younger child. Modification to the FUF standard scope and labelling is needed to appropriately address those differences.

However, the United States found it difficult to respond to these questions and suggests that we consider starting with a preamble statement to set the stage for the entire document for clarity. We consider it important to clearly identify up-front that there are two categories of products intended for two different populations and create two separate sections for them. By doing so, there would be parallel tracks for each category of product that can be individualized as needed. For example, the essential composition and quality factors and the labelling requirements for each product category can be specified as appropriate for the intended population.

Borrowing the organization and format from the Infant Formula Standard, we suggest the following for consideration:

STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS 6 TO 12 MONTHS OF AGE AND [NAME OF PRODUCT] FOR YOUNG CHILDREN 12 TO 36 MONTHS OF AGE

SECTION A: REVISED STANDARD FOR FOLLOW-UP FORMULA PRODUCTS FOR OLDER INFANTS PREAMBLE:

This standard is divided into two sections. Section A refers to products for older infants (6 to 12 months of age) and Section B refers to products for young children (12 to 36 months of age).

1. SCOPE
The items in the scope section can now be tailored as appropriate for the two categories of products. Section 1- Scope (page 71 of CP2):

The United States would consider aligning the scope for follow-up formula for older infants (6-12 months) with the current Codex labelling requirements for Infant Formula. Additionally, for young children (12-36 months), we would consider aligning elements contained in the scope with the Infant Formula Standard. As listed in Table 23 (page 71 of CP2), this would include Application, Intended Role of Products, Exclusions, Form of the Food, and Use Must Be in Accordance with Other Policies. The United States recommends that the scope and labelling provisions be clearly stated with modifications addressing the different uses of the product category based on the age of the intended consumer to ensure the product is not misused or misrepresented.

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

Please provide justification for your answer.

Regarding Section 9- Labelling (page 72-73 of CP2):
The United States considers the general provisions as identified in the documents listed in the introduction to the labeling provisions from the Infant Formula Standard shown in the next paragraph apply to the follow-up formula products. The specific topics such as Name of the Food, List of Ingredients, Declaration of Nutritive Value, Date Marking and Storage Instructions, Information for Use, and Additional Labelling Requirements can then be addressed in the existing format for labelling, which would still largely apply and any modifications needed could be done for each category of

product.
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 apply to infant formula and formula for special medical purposes 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. In addition to these requirements the following specific provisions apply:

9. LABELLING
Throughout the text of the standard, we note that the word "food" should be changed to "product" to be consistent with the decision made at the last Committee meeting. It was decided then that follow-up formula will be referred to as a product not food in the definitions section 2.1.1.

The United States agrees with the eWG Chairs proposal to defer consideration on naming the food (Section 9.1) until definition 2.1.1 is finalized, noting that the definition will be considered following sufficient clarity on the composition of follow-up formula for young children.

Further, the United States notes there is a need for label statement differences since there are two different products (older infant and young children). We support the use of distinct names for the two products now included in this standard, one for older infants and one for young children. We note that the Chairs have deferred naming the products in this consultation but we consider it important that the products are clearly distinguishable from one another. We note that the word "formula" implies a product that meets the nutritional requirements of the ***infant*** *consumer. The definition of infant formula in the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72 – 1981) is "a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding". Thus, the term "formula" has become associated with a product that meets the nutritional requirements of infants.*

We strongly suggest consideration be given to the product for young children having a different name that does not include the word formula, since it does not provide by itself the normal nutritional requirements of the target group aged 12-36 months. The use of the word "formula" would be misleading, and the product could potentially be fed incorrectly as a complete replacement for all foods. The proposed composition of follow-up formula for young children only requires 13 nutrients unlike the Infant formula Standard and the proposed follow-up formula for older infants both require 32 nutrients.

Once the products have a clear identity and labelling formats are considered, a discussion with the CCFL (Codex Committee on Food Labeling) for their advice would be helpful. However, we have provided some suggestions below for consideration and are open to further discussion.

The United States suggests that Section 9.4: Date Marking and Storage Instructions (page 72 of CP2) stating that "where practicable, storage instructions shall be in close proximity to the date marking" to the FUF standard for 6-12 month older infants and 12-36 young children for the safety of the products be considered for inclusion.

Additionally, the US suggests that Section 9.5: Information for Utilization (pages 72-73 of CP2) with the Codex Standard for Infant Formula for safety reasons which would include Good Hygienic Practice, disposal after preparation, clear graphic instructions for preparation, and warning about health hazards of inappropriate preparation, storage, and use for the older infant 6-12 months be aligned.

The United States considers the statement that follow-up formula shall not be introduced before the sixth month of life as information that should be on the labels of products for older infants. A parallel statement should be included on the labels of the products for young children 12 to 36 months of age to indicate that those products should not be introduced before 12 months of age. Additionally, we consider that the statement indicating that both age groups that are fed these products "shall receive other foods" should be retained in this standard and support discussion regarding the inclusion of

references to and provisions from other appropriate Codex Standards that are applicable for the products' safe production and use.
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: *The US notes that the exploration of the labeling issues for this product, as laid out by the eWG, has been comprehensive. Our concerns have been discussed above.*
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: *The United States considers labelling and marketing/advertising to be two different entities. While labelling is an essential part of the Codex Standard for FUF and required to promote accurate identification and safe and appropriate use of the product, the WHA resolutions relate to marketing. The Infant Formula Standard refers to the WHA 54.2 under section 1.4 of the scope and it could be considered for the 6-12 month old product, if the Committee accepts this product as a breast milk substitute. The product for the 12 -36 month old is not a breast milk substitute and we do not consider it necessary to include the reference in the scope with regard to this product category.*
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 United States considers that the recent Guidance from the WHO has limited applicability to the Codex standard on Follow-up formula. Codex standards do not, as a rule, include restrictions or requirements regarding marketing and promotion. However, we recognize that there is research that shows that mothers are confused regarding the use of these products [16], which underscores the importance of distinct product names and clear instructions for use.*
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: *The United States considers modifications are needed to the current drafting of Section 9.6 of the current follow-up formula standard. As previously stated, we consider the Codex Standard for Infant Formula should serve as the model for the Codex Standard for Follow-Up Formula for the older infant (ages 6-12 months). However, in regards to the Codex Standard for Follow-Up for the young child (12-36 months), we consider adding language from the International Code of Marketing of Breast-Milk Substitutes (Article 9) could confuse consumers as the 12-36 month product is not a breast-milk substitute and would not require all provisions in the IF standard.*

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