Review of the Follow-up Formula Standard

(CXS 156 – 1987)

2019 Consultation Paper – Outstanding Aspects of the Standard

Responses due **Thursday 28 April**

INFANT NUTRITION COUNCIL AUSTRALIA NEW ZEALAND

2 DEXTROSE EQUIVALENT

QUESTION 1: Are you aware of a DE limit being used for carbohydrate sources for products for young children, follow-up formula or for infant formula in national/regional regulations? Please provide references to support your response. Please also comment on how any limits are adhered to and enforced.

RESPONSE:

INC is aware of provisions in the EU relating to specific composition requirements for infant formula and follow-on formula that set a maximum Dextrose Equivalent of 32 for added glucose syrup or dried glucose syrup (Commission Delegated Regulation (EU) 2016/127). These provisions apply to added glucose syrup or dried glucose syrup when used as ingredients in both milk and soya protein-based formulas intended for infants. They do not apply to the final product as such but rather are prescribed in conjunction with other parameters relating to the carbohydrate content of the products concerned. The EU regulation also allows the addition of sucrose, fructose and honey (separately or as a whole) to follow-on formula within a limit of 20% of total carbohydrates.

There is no specific EU harmonised rule for [Name of the product] for young children.

Reference for infant formula: Annex 1, Section 8 of Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

Reference for follow-on formula: Annex 2, Section 6 of Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

We understand from ISDI that enforcement agencies in the EU Member states ensure manufacturers meet the provisions by controlling the limit set for glucose in the finish product.

For [Name of the product] for young children considered in the revision of the Codex Standard for Follow-up Formula, the limit set for mono and disaccharides, other than lactose, set by default at 2.5g/100 kcal in the product, will be used by national controlling Authorities.

QUESTION 2: Please indicate your preference from the two options proposed. If you do not support either of the proposed options, please provide an alternative proposal with justification.	
Option 1: The limit for mono-and disaccharides and the prohibition on using sucrose and fructose are adequate to limit the sweetness of products not based on milk protein for young children and no further restrictions are required. ☒	**Option 2:** Include that glucose polymers should be the preferred carbohydrates for products not based on milk protein. ☐
RESPONSE: **INC prefers option1.** INC supports the use of maltodextrins and glucose syrups or dried glucose syrup with the limit of 2.5g/100 kcal set by default for mono and di-saccharides other than lactose in the product. INC considers the limit of mono and di-saccharides (other than lactose), together with a prohibition of using sucrose and fructose, will be adequate measures to limit the sweetness of [name of product] for young children and no further restrictions are required. Of the two options proposed in the consultation paper, Option 1 is most closely aligned with the wording used in the Infant Formula Standard (CODEX STAN 72-1981) which does not provide specific provision for non-milk-based formula in the carbohydrate section. However, INC could also accept Option 2 if the majority of submitters support this Option.	

3 SENTENCE IN SECTION 3.2.1 for [name of product] for young children

QUESTION 3: Are you aware of substances or ingredients that are not classified as carbohydrates or food additives that could be added with the purpose to impart or enhance sweet taste in [name of product] for young children? Please provide the name(s) of such substances and their potential sources.
RESPONSE: INC is not aware of any substances or ingredients that are not classified as carbohydrates or food additives that are added with the purpose to impart or enhance sweet taste in [name of product] for young children. **INC considers that the sentence "[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of the product].]" should be deleted.** The paragraphs 3.2.1 of the "optional ingredients" section deals with the addition of ingredients or substances to achieve a, "particular nutrition purpose" in relation to beneficial effect. The purpose of their addition must be nutritional. Since a sweet taste is not a nutritional purpose, the added text in square brackets is inconsistent with the rationale for paragraphs 3.2.1. Optional ingredients added that contain mono- and/or disaccharides, for example oligosaccharides, are regulated as for mono- and disaccharides from any other sources, by the maximum limits set for carbohydrates and mono and di-saccharides in 3.1.2b. INC agrees with the comment of the eWG Chair in section 4.2.5.1 of the consultation paper that sweeteners are not currently permitted in Follow-up Formula.

4 WORK FOR FURTHER CONSIDERATION

General comments:

Several of the additional sections in the current Follow-up formula Standard have yet to be considered by CCNSFDU. These sections, which are still part of commodity standards according to the Procedural Manual, are in some areas addressed in other Codex Standards or Guidelines.

However, INC supports retaining the text of these sections in the current Follow-up Formula Standard, drawing on the text of these sections from the Infant Formula Standard if relevant and amending the text to ensure applicability for the appropriate age group, where necessary.

4.2.1 Purity Requirements

QUESTION 4a: Do you agree with the provisions for purity requirements in the current Follow-up Formula Standard being retained for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation noting that the wording needs to be amended to reflect the relevant age group as follows: "All ingredients shall be clean, of good quality, safe and suitable for ingestion by **<u>older</u>** infants ~~from the 6th month on and young children~~. They shall conform with their normal quality requirements, such as colour, flavour and odour."	
QUESTION 4b: Do you agree with the provisions for purity requirements in the current Follow-up Formula Standard being retained for [name of product] for young children? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation noting that the wording needs to be amended to reflect the relevant age group as follows: "All ingredients shall be clean, of good quality, safe and suitable for ingestion by **<u>young children</u>** ~~infants from the 6th month on and young children~~. They shall conform with their normal quality requirements, such as colour, flavour and odour."	

4.2.2 Vitamin Compounds and Mineral Salts

QUESTION 5a: Do you agree with the recommendation to retain provisions 3.4.2.1 and 3.4.2.2 of the current Follow-up Formula Standard (relating to vitamin compounds and mineral salts) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation.	

QUESTION 5b: Do you agree with the recommendation to retain only provision 3.4.2.1 of the current Follow-up Formula Standard (relating to vitamin compounds and mineral salts) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation. This is similar to additives where the current FUF Standard indicates, “Within the limits for sodium in Section 3.2.6” {composition section of the Standard}. Since there is no maximum limit for sodium in the revised Follow- up Formula Standard for [Name of the product] for young children, and the sodium maximum in the revised Follow-up Formula Standard for older infants is appropriate for infants and not young children, it is redundant including this reference both in the additives section and the section on vitamins and minerals.	

4.2.3 Consistency and Particle Size

QUESTION 6a: Do you agree with the recommendation to retain provision 3.5 in the current Follow-up Formula Standard (relating to consistency and particle size) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation.	
QUESTION 6b: Do you agree with the recommendation to retain provision 3.5 in the current Follow-up Formula Standard (relating to consistency and particle size) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation.	

4.2.4 Specific Prohibitions

QUESTION 7a: Do you agree with the recommendation to retain provision 3.6 in the current Follow-up Formula Standard (relating to specific prohibitions) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation.	

QUESTION 7b: Do you agree with the recommendation to retain provision 3.6 in the current Follow-up Formula Standard (relating to specific prohibitions) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation.	

4.2.5 Food Additives (excluding flavourings)

QUESTION 8a: Do you agree with the rules as described for follow-up formula for older infants?	
☒ Yes, provided safety text amended.	☐ No
RESPONSE: INC agrees with the principle of providing guidance, or "rules" to guide discussion in this section on Food Additives, as related to 1) conformity with Preamble of the GSFA; 2) ongoing Alignment work for additives in CCNFSDU Standards; and 3) ongoing work on the Framework for Technological Justification. INC supports the "rules" as proposed for 2) ongoing Alignment work for additives, and 3) ongoing work on the Framework for Technological Justification. Within the "Conformity to GSFA" rule, the sub-part (i) related to Safety, as currently proposed, may be interpreted to mean that JECFA would/has conducted safety assessments specifically for when the additives are used in Follow Up Formula. This is not the case, although there are JECFA safety assessments available for the additives currently permitted for Follow Up Formula. We suggest modification of the text to be consistent with the text in section 3.1(a) of the Preamble to the GSFA: 3.1 GSFA text: 3.1 Food Additive Safety a) Only those food additives shall be endorsed and included in this Standard that, so far as can be judged on the evidence presently available from JECFA, present no appreciable health risk to consumers at the use levels proposed. Current proposal: i) **Safety**: Only food additives which have been evaluated by JECFA and found acceptable and safe for use in this category of foods should be permitted INC Suggested modified text: i) **Safety:** Only those food additives shall be permitted that, so far as can be judged on the evidence presently available from JECFA, present no appreciable health risk to consumers at the use levels proposed.	

QUESTION 8b: Do you agree with the rules as described for [name of product] for young children?	
☒ Yes, provided safety text amended.	☐ No
RESPONSE: INC agrees with the "rules" as proposed for 2) ongoing Alignment work for additives, and 3) ongoing work on the Framework for Technological Justification but suggested modified wording for rule relating to Safety as detailed in response 8a.	

QUESTION 9a: Do you agree that the current permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard are retained for follow-up formula for older infants? If not, please provide justification and an alternative approach.	
☒ Yes	☐ No
RESPONSE: INC agrees that the current permissions for food additives in the current Follow-up Formula Standard be retained for follow-up formula for older infants. INC notes that flavourings will be dealt with in a separate section in the revised Standard.	
QUESTION 9b: Do you agree that the current permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard are retained for [name of product] for young children? If not, please provide justification and an alternative approach.	
☒ Yes	☐ No
RESPONSE: INC agrees that the current permissions for food additives in the current Follow-up Formula Standard be retained for [name of product] for young children. INC notes that flavourings will be dealt with in a separate section in the revised Standard.	

QUESTION 10: Do you agree with the administrative changes (i – iv) to be made to the current list of food additives? If not, please provide justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees amendment is required in relation to food additives. INC could agree with administrative changes to the current list of food additives and supports the draft of the administrative changes prepared by ISDI for consideration by the eWG (included as Attachment A). Alternatively, INC could also agree to making reference to the additive provisions in the appropriate food category in the GSFA within the Food Additives section of the revised Follow Up Formula Standard, rather than including the Table (with administrative changes). Referencing the GSFA has the following attributes: • It is consistent with the Codex Procedural Manual to reference the GSFA in Codex Standards unless there is sound rationale to do otherwise. • It is enabled due to the high level of alignment of food additive provisions in current FUF Standard and GSFA FC 13.1.2 (Follow Up Formulae). One-to-one correspondence of the GSFA food category (13.1.2) and the Follow Up Formula Standard facilitates the assessment of additive provisions. • It supports expediting completion of the revision of the FUF Standard. Any minor misalignment in additive provisions can be addressed within the upcoming Alignment work (alignment of additive provisions in CCNFSDU standards with GSFA FC).	

If this alternative option is progressed, then INC concurs with ISDI in suggesting the following text:

> **4. FOOD ADDITIVES**
> Acidity regulators, antioxidants, emulsifiers, packaging gases and thickeners used in accordance with Table 1 and Table 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in food category 13.1.2 (Follow-Up Formulae) and its parent food categories are acceptable for use in foods conforming to this Standard.

INC notes that there are several additive provisions that will require adjustment in order to secure alignment of provisions in the Standard with those in GSFA food category 13.1.2 (including packaging gases, sodium, CITREM). These can be addressed within the upcoming Alignment work, and through subsequent work of the GSFA WG within CCFA.

4.2.5 Carry-over of food additives and Nutrient Carriers

QUESTION 11a: Please indicate your preferred option for follow-up formula for older infants and provide justification for your response.

If you do not agree with either option, please provide an alternative suggestion and justification for your response.

Option 1: Maintain status quo ☐	Option 2: Adopt the text from the Infant Formula Standard and Standard for Processed Cereal- based Foods for Infants and Young Children ☒ Yes

RESPONSE:

INC supports the adoption of the text from the Infant formula Standard and the Standard for Processed Cereal-based Foods for older Infants and young children respectively should the approach suggested in Q10 by the eWG Chair be progressed. The text should read as follows:

> **4. FOOD ADDITIVES**
> Food additives listed in Table 1 and Table 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in Food Category 13.1.2 (Follow-Up Formulae)) may be used in Follow Up Formula for Older Infants to the maximum limits given in Food Category 13.1.2.
>
> Only the food additives listed in this Section or in the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in section XX of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:
>
> a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
>
> b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995).

If the alternative approach, to make reference to the additive provisions in the GFSA suggested by INC in response to Q10, is progressed, then INC supports the drafting in the Annex based very largely on that proposed by ISDI.

INC notes that in the consultation paper (section 4.2.5.5) the section that should be referenced is 4.3 not 4.1.

QUESTION 11b: Please indicate your preferred option for [name of product] for young children and provide justification for your response. If you do not agree with either option, please provide an alternative suggestion and justification for your response.	
Option 1: Maintain status quo ☐	Option 2: Adopt the text from the Infant Formula Standard and Standard for Processed Cereal- based Foods for Infants and Young Children ☒ Yes

RESPONSE:

INC supports the adoption of the text from the Infant formula Standard and Standard for Processed Cereal-based Foods for older Infants and young children respectively should the approach suggested in Q10 by the eWG Chair be progressed.

The proposed text might read as follows:

> **4. FOOD ADDITIVES**
> Food additives listed in Table 1 and Table 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in Food Category 13.1.2 (Follow-Up Formulae)) may be used in [Name of the product] for young children to the maximum limits given in Food Category 13.1.2.
>
> Only the food additives listed in this Section or in the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in section XX of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:
>
> a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
>
> b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995).

If the alternative approach, to make reference to the additive provisions in the GFSA suggested by INC in response to Q10, is progressed, then INC supports the drafting in the Annex which is based largely on that proposed by ISDI.

4.2.6 Flavourings

QUESTION 12a: Do you agree that the provisions for flavourings contained within the current Follow-up Formula Standard are retained for follow-up formula for older infants? Please provide justification for your response.	
☒ Yes	☐ No

RESPONSE:

INC supports retention of the permitted flavourings for use in Follow Up Formula for older infants as listed in the current Codex Follow-up Formula Standard:

- each flavouring has a JECFA safety assessment, confirming there are no safety concerns at the proposed levels of use;
- each flavouring has established specifications for identity and purity;
- a very limited set of flavourings is currently permitted in the current text of Follow-up

Formula Standard.

Other foods for the same age range (older infants) may also contain similar flavourings (canned baby foods and processed cereals-based foods).

Flavourings are generally used at lower concentrations in foods for older infants compared with foods for the general population and primarily for the purpose of modifying undesirable flavour characteristics inherent to a product to improve palatability.

INC suggests the following text:

"The flavourings used in products covered by this standard should comply with the *Guidelines for the use of Flavourings* (CAC/GL 66-2008). The following flavourings may be used:
- Natural Fruit Extracts and vanilla extract: GMP
- Ethyl vanillin: 5mg/100ml."

QUESTION 12b: Do you agree that the provisions for flavourings contained within the current Follow-up Formula Standard are retained for [name of product for young children? Please provide justification for your response.

☒ Yes	☐ No

RESPONSE:

INC supports retention of the permitted flavourings for use in [name of product] for young children as listed in the current Codex Follow-up Formula Standard:

INC supports the use of the flavourings stated in the current Codex Follow-up Formula Standard for the following reasons:
- each flavouring has a JECFA safety assessment, confirming there are no safety concerns at the proposed levels of use;
- each flavouring has established specifications for identity and purity;
- young children consume many products that contain flavourings;
- flavourings remain necessary in these foods to support taste development and food acceptance;
- flavourings are generally used at lower concentrations in foods for older infants and young children compared with foods for general population.
- where flavourings are used in foods for young children, these are required to:
    - supplement, restore or fortify an existing flavour;
    - impart their flavour to the finished product;
    - modify any undesirable flavour characteristics inherent to a product.

INC suggests the following text:

"The flavourings used in products covered by this standard should comply with the Guidelines for the use of Flavourings (CAC/GL 66-2008). The following flavourings may be used:
- Natural Fruit Extracts and vanilla extract: GMP
- Ethyl vanillin: 5mg/100ml."

4.2.7 Contaminants

QUESTION 13a: Do you agree with the recommendation to adopt provision 5 from the more recently revised Infant Formula Standard (relating to contaminants) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.
☒ Yes ☐ No
RESPONSE: INC agrees with the recommendation.
QUESTION 13b: Do you agree with the recommendation to adopt provision 5 from the more recently revised Infant Formula Standard (relating to contaminants) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.
☒ Yes ☐ No
RESPONSE: INC agrees with the recommendation.

4.2.8 Hygiene

QUESTION 14a: Do you agree with the recommendation to adopt provisions 6.1 and 6.2 from the more recently revised Infant Formula Standard (relating to hygiene) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.
☒ Yes ☐ No
RESPONSE: INC agrees with the recommendation. The language in the Infant Formula Standard is consistent with how commodity standards have been updated. It provides the same meaning but with more clarity than the language in the Follow-up Formula Standard.
QUESTION 14b: Do you agree with the recommendation to adopt provisions 6.1 and 6.2 from the more recently revised Infant Formula Standard (relating to hygiene) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.
☒ Yes ☐ No
RESPONSE: INC agrees with the recommendation. The language in the Infant Formula Standard is consistent with how commodity standards have been updated. It provides the same meaning but with more clarity than the language in the Follow-up Formula Standard.

4.2.9 Packaging

QUESTION 15a: Do you agree with the recommendation to retain provisions 7.1 and 7.2 in the current Follow-up Formula Standard (relating to packaging) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.	
☒ Yes, in part	☐ No

RESPONSE:

INC agrees in part with the recommendation.

We note that section 4.2.5.2 (iv) in the Consultation Paper reads: “Move the permissions for packaging gases (i.e. carbon dioxide and nitrogen) from Section 7 Packaging to Section 4 Food Additives”. In recommending that the permissions for packaging gases *move*, this means deleting reference to carbon dioxide and nitrogen from section 7.1 and adding it to the Food Additives section.

We do not support moving the reference but rather leaving reference to the packaging gases where they currently occur and adding reference to packaging gases to the Food Additives section, referencing carbon dioxide and nitrogen in both sections (Food Additives and 7.1 Packaging). This will avoid any confusion about permission for use of these food additives which might otherwise arise.

QUESTION 15b: Do you agree with the recommendation to retain provisions 7.1 and 7.2 in the current Follow-up Formula Standard (relating to packaging) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.	
☒ Yes, in part	☐ No

RESPONSE:

INC agrees in part with the recommendation.

As noted in our response to question 15a, we note that section 4.2.5.2 (iv) in the Consultation Paper reads: “Move the permissions for packaging gases (i.e. carbon dioxide and nitrogen) from Section 7 Packaging to Section 4 Food Additives”. In recommending that the permissions for packaging gases move, this means deleting reference to carbon dioxide and nitrogen from section 7.1, and adding it to the Food Additives section.

We do not support moving the reference but rather leaving reference to the packaging gases where they currently occur and adding reference to packaging gases to the Food Additives section, referencing carbon dioxide and nitrogen in both sections (Food Additives and 7.1 Packaging). This will avoid any confusion about permission for use of these food additives which might otherwise arise.

4.2.10 Fill of container

QUESTION 16a: Do you agree with the recommendation to retain provisions 8 (i), (ii) and (iii) in the current Follow-up Formula Standard (relating to fill of containers) for follow-up formula for older infants, noting the revised level of 5 oz. (from the previous value of 5 ½ oz.)?

If not, please provide an alternative approach and justification for your response.

☒ Yes	☐ No

RESPONSE:

INC agrees with the recommendation, but very reluctantly with respect to the revised fill levels stated.

This revision is inconsistent with the use of a standard number of significant figures advocated by industry for stating limits in preference to arbitrary rounding rules.

We remain very disappointed that CRD5 tabled at CCNSDU40 outlining recommended rounding rules was prepared without prior discussion on the rules proposed with industry to ascertain their impact. We note the CRD referred to “a reasonable level of specificity” when greater specificity and consistency of approach could have been achieved; and that it stated “the logic that has been applied aligns fairly well with the current drafting and also with other international regulations for follow-up formula”, a statement we consider is not correct.

INC is very concerned that these rounding rules may now be used as a precedent for other standards and regulations and is strongly opposed to this possibility, including for the FSANZ review of Infant Formula Products under Proposal P1028.

QUESTION 16b: Do you agree with the recommendation to retain provisions 8 (i), (ii) and (iii) in the current Follow-up Formula Standard (relating to fill of containers) for [name of product] for young children, noting the revised level of 5 oz. (from the previous value of 5 ½ oz.)?

If not, please provide an alternative approach and justification for your response.

☒ Yes	☐ No

RESPONSE:

As above, INC reluctantly agrees with the recommendation but very reluctantly with respect to the revised fill levels stated.

This revision is inconsistent with the use of a standard number of significant figures advocated by industry for stating limits in preference to arbitrary rounding rules.

We remain very disappointed that the CRD5 tabled at CCNSDU40 outlining recommended rounding rules was prepared without prior discussion on the rules proposed with industry to ascertain their impact. We note the CRD referred to “a reasonable level of specificity” when greater specificity and consistency of approach could have been achieved; and that it stated “the logic that has been applied aligns fairly well with the current drafting and also with other international regulations for follow-up formula”, a statement we consider is not correct.

INC is very concerned that these rounding rules may now be used as a precedent for other standards and regulations and is strongly opposed to this possibility, including for the FSANZ review of Infant Formula Products under Proposal P1028.

4.2.11 Methods of analysis and sampling

QUESTION 17a: Do you agree with the recommendation to retain provision 10 in the current Follow-up Formula Standard (relating to methods of analysis and sampling) for follow-up formula for older infants? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation to retain provision 10 in the current Follow-up Formula Standard (relating to methods of analysis and sampling) for follow-up formula for older infants. Both the Infant Formula Standard and the current Follow-up Formula Standard include the same requirements for methods of analysis and sampling. This section reads “For checking the compliance with this Standard, the methods of analysis contained in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) relevant to the provisions in this standard, shall be used”.	

QUESTION 17b: Do you agree with the recommendation to retain provision 10 in the current Follow-up Formula Standard (relating to methods of analysis and sampling) for [name of product] for young children? If not, please provide an alternative approach and justification for your response.	
☒ Yes	☐ No
RESPONSE: INC agrees with the recommendation to retain provision 10 in the current Follow-up Formula Standard (relating to methods of analysis and sampling) for [name of product] for young children. Both the Infant Formula Standard and the current Follow-up Formula Standard include the same requirements for methods of analysis and sampling. This section reads “For checking the compliance with this Standard, the methods of analysis contained in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) relevant to the provisions in this standard, shall be used”.	

Annex A

Revision of Follow up Formula Standard: Food Additives

It is necessary to update the food additives section in the Follow-up Formula Standard (STAN 156-1987) to ensure consistency with other Codex texts and alignment work with the GSFA. A table, such as is replicated below, could be included or, alternatively, a reference to the GSFA could be made together with consequential minor amendments where the GSFA and the FUF Standard are not aligned. Suggested text for reference to the GSFA is shown further below.

4. FOOD ADDITIVES

INS	Additive	Maximum level in 100mL of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1g
410	Locust bean gum (carob bean gum	0.1g
1412	Distarch phosphate	0.5g singly or in combination in soy-based products only; 2.5g singly or in combination in hydrolysed protein and/or amino acid based liquid products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03g singly or in combination with other thickeners in milk and soy-based products only; 0.1g singly or in combination with other thickeners in hydrolysed protein and/or amino acid based liquid products only
440	Pectins	1g
4.2 Emulsifiers		
322	Lecithin	0.5g
471	Mono- and Di-glycerides	0.4g
4.3 Acidity regulators		
500ii	Sodium hydrogen carbonate	Limited by GMP**
500i	Sodium carbonate	
331i	Sodium citrate = sodium dihydrogen citrate	
331iii	Sodium citrate = trisodium citrate	
524	Sodium hydroxide	
501ii	Potassium hydrogen carbonate	Limited by GMP
501i	Potassium carbonate	
332i	Potassium citrate = potassium dihydrogen citrate	
332ii	Potassium citrate = tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	L(+) Lactic acid	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidants		
307b		3 mg singly or in combination
307a, c	α-tocopherol	
304	L-ascorbyl palmitate	5 mg singly or in combination, Expressed as ascorbic acid (INS 300, 301, 302, 304)
301	Sodium ascorbate**	
302	Calcium ascorbate	
300	Ascorbic acid, L-	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

**INC suggests that the limits for sodium in Section x.x.x be retained for follow-up formula for older infants only.

Option to Consider as Text in the Revised FUF Standard: Reference the GSFA

Use the General Standard for Food Additives by reference in the Food Additives section of the Standard for FUF.

4. FOOD ADDITIVES

Acidity regulators, antioxidants, emulsifiers, packaging gases and thickeners used in accordance with Table 1 and Table 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in food category 13.1.2 (Follow-Up Formulae) and its parent food categories are acceptable for use in foods conforming to this Standard.

Only the food additives listed in this Section or in the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in section XX of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995).