



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

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**REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)**  
**PROPOSED DRAFT FOLLOW UP FORMULA FOR OLDER INFANTS AND [PRODUCT] FOR YOUNG CHILDREN**

Prepared by the Electronic Working Group led by New Zealand, France and Indonesia

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2019/78-NFSDU available on the Codex webpage/Circular Letters 2019:

<http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>.

## INTRODUCTION

At the 40th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU40), the Committee agreed to continue work on the revision of the Follow-up Formula Standard ([CXS 156-1987](#)) and to:

- advance Section A: follow up formula for older infants to Step 5 for adoption by CAC42 ([Appendix III REP19/NFSDU](#));
- send the labelling provisions for follow up formula for older infants to CCFL45 for endorsement;
- defer discussion on Section B: product definition and labelling of [product] for young children ([Appendix IV REP19/NFSDU](#)), the structure of the Standard(s) and preamble(s) for discussion at CCNFSDU41; and
- re-establish the EWG chaired by New Zealand and co-chaired by France and Indonesia and working in English to address the issue of DE and the sentence in square brackets in section 3.2.1 (See REP19/NFSDU [para 33](#)) and to complete the remaining sections as follows;
  - purity requirements
  - vitamin compound and mineral salts
  - consistency and particle size
  - specific prohibitions
  - food additives
  - contaminants
  - hygiene
  - packaging
  - fill of container
  - methods of analysis and sampling

Since CCNFSDU40, Section A: follow up formula for older infants was adopted at Step 5 by CAC42 with the changes proposed by CCFL45, noting that the issue of cross promotion has been returned to CCNFSDU for further discussion.

## CONDUCT OF THE ELECTRONIC WORKING GROUP (EWG) 2019

The eWG (list of participants is presented in APPENDIX III: LIST OF 2019 EWG PARTICIPANTS) has considered one consultation paper during 2019. The consultation paper was posted on the Codex online platform in March for a six-week consultation period. Based on the responses to that paper, the Chair was of the view that a second round of consultation was not necessary.

Please note the following abbreviations used throughout this paper:

CM: Codex Member                      CMO: Codex Member Organisation

CO: Codex Observer                      eWG: Electronic Working Group

Infant Formula Standard: *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-181)

GSFA: *General Standard for Food Additives* (CXS 192-1995)

## CONCLUSIONS

The Chair of the eWG has used feedback from the 2019 eWG consultation to prepare this Agenda Paper, which contains 15 recommendations in Appendix I covering the proposal on dextrose equivalent (DE) for products not based on milk protein in footnote 4 for [name of product] for young children and the sentence in square brackets regarding substances imparting or enhancing a sweet taste in section 3.2.1, followed by the remaining sections of the standard.

## PROPOSED TIMELINE

November 2019	Consideration of the draft standard and advancement of the scope, labelling, name of product, and definition sections for [name of product] for young children, as well as the remaining sections of the standard for both product categories (including the structure and preamble) to Step 5
July 2020	CAC progression of scope, labelling, name of product, and definition sections for [name of product] for young children, as well as the remaining sections of the standard for both product categories (including the structure and preamble) to Step 5
December 2020	Completion of the standard and advancement to Step 8 for adoption by CAC
July 2021	CAC adoption of final standard

**Table of Contents**

<b>AGENDA ITEM 4D CX/NFSDU 19/41/5</b> .....	<b>1</b>
<b>JOINT FAO/WHO FOOD STANDARDS PROGRAMME</b> .....	<b>1</b>
<b>CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES</b> .....	<b>1</b>
<b>REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987) PROPOSED DRAFT FOLLOW UP FORMULA FOR OLDER INFANTS AND [PRODUCT] FOR YOUNG CHILDREN</b> .....	<b>1</b>
<b>INTRODUCTION</b> .....	<b>1</b>
CONDUCT OF THE ELECTRONIC WORKING GROUP (EWG) 2019.....	2
CONCLUSIONS.....	2
PROPOSED TIMELINE .....	2
<b>APPENDIX I: DISCUSSION AND RECOMMENDATIONS OF EWG</b> .....	<b>4</b>
<b>1 DEXTROSE EQUIVALENT</b> .....	<b>4</b>
<b>2 SENTENCE IN SECTION 3.2.1 FOR [NAME OF PRODUCT] FOR YOUNG CHILDREN</b> .....	<b>6</b>
<b>3 REMAINING SECTIONS OF THE STANDARD</b> .....	<b>7</b>
3.1 PURITY REQUIREMENTS .....	7
3.2 VITAMIN COMPOUNDS AND MINERAL SALTS.....	8
3.3 CONSISTENCY AND PARTICLE SIZE.....	9
3.4 SPECIFIC PROHIBITIONS .....	10
3.5 FOOD ADDITIVES (EXCLUDING FLAVOURINGS) .....	11
3.5.1 Carry-over of food additives and nutrient carriers.....	14
3.6 FLAVOURINGS .....	16
3.7 CONTAMINANTS.....	17
3.8 HYGIENE .....	18
3.9 PACKAGING.....	20
3.10 FILL OF CONTAINER.....	21
3.11 METHODS OF ANALYSIS AND SAMPLING .....	22
<b>APPENDIX II: SECTION 4 FOOD ADDITIVES</b> .....	<b>24</b>
<b>APPENDIX III: LIST OF 2019 EWG PARTICIPANTS</b> .....	<b>26</b>

## APPENDIX I: DISCUSSION AND RECOMMENDATIONS OF EWG

### 1 DEXTROSE EQUIVALENT

#### Background

At CCNFSDU40 the Committee reached an agreement on parts of footnote 4 for [name of product] for young children, including the limit for mono- and disaccharides and that sucrose and/or fructose should not be added to the product. It was further proposed that, for products not based on milk protein, a reference to carbohydrate sources contributing to the sweet taste should be limited by a DE value not higher than 15. Additionally it was decided to move the reference to 'other non-carbohydrate ingredients' to section 3.2.1. under Optional ingredients.

Two options referring to the DE limit of 15 were left in square brackets for the 2019 eWG to consider and for discussion and decision at CCNFSDU41 ([REP19/NFSDU](#) Appendix II). These are replicated below in bold:

***<sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. [For products not based on milk protein, carbohydrate sources (like starch) with an average DE of 15 should be used. OR For products not based on milk protein, a combination of carbohydrate sources giving an average dextrose equivalent not higher than DE15 (corresponding to the relative sweetness of lactose), should be preferred.] (for consideration by the EWG on follow-up formula)***

*Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.*

The aim of the proposed DE limit for the carbohydrate sources used in the manufacture of products for young children not based on milk protein, is to ensure that those carbohydrate sources are no sweeter than lactose which is the preferred carbohydrate in products based on milk protein.

The Chair addressed the DE proposals in the 2019 consultation paper, which concluded that setting a DE limit of 15 for carbohydrate sources on the basis of having a similar relative sweetness as lactose is arbitrary as there is no direct link with the DE value of a carbohydrate and its relative sweetness<sup>1</sup>. Relative sweetness in itself is not an absolute analytical measure<sup>2</sup> and lactose has been reported to have a relative sweetness range of 15-40<sup>1</sup>.

The Chair proposed further two alternative options for the eWG to consider:

**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.

*~~<sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. [For products not based on milk protein, carbohydrate sources (like starch) with an average DE of 15 should be used. OR For products not based on milk protein, a combination of carbohydrate sources giving an average dextrose equivalent not higher than DE15 (corresponding to the relative sweetness of lactose), should be preferred.] (for consideration by the EWG on follow-up formula)~~*

*Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.*

**Option 2:** Include that glucose polymers should be the preferred carbohydrates for products not based on milk protein.

*<sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. [For products not based on milk protein glucose polymers should be the preferred carbohydrates used.] [For products not based on milk protein, carbohydrate sources (like starch) with an average DE of 15 should be used. OR For products not based on milk protein, a combination of carbohydrate sources giving an average dextrose equivalent not higher than DE15 (corresponding to the relative sweetness of lactose), should be preferred.] (for consideration by the EWG on follow-up formula)*

<sup>1</sup> Clemens RA, Jones JM, Kern M, Lee S-Y, Mayhew EJ, Slavin JL, Zivanovic S (2016). Functionality of sugars in foods and health. *Comprehensive Reviews in Food Science and Food Safety* 15:433- 470.

<sup>2</sup> AIB (American Institute of Baking) (2016). *Bakery science: Sweeteners – Composition, types, and functions*. 2016; 1-10.

*Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.*

## EWG views

The eWG was asked whether they were aware of a DE limit being used for carbohydrate sources for products for young children, follow-up formula, or for infant formula in any national or regional regulations. None were mentioned, apart from the EU regulations for infant and follow-up formula which Switzerland are also applying in their national legislation. The EU regulations were described in the consultation paper.

Approximately two-thirds of eWG respondents (13 CM, 2 CO) supported Option 1 put forward in the consultation paper and one-third (7 CM, 1 CMO) supported Option 2. Additionally one CM considered the options complimentary and could support either, and one CO supported neither of the options proposed.

Furthermore the CMO suggested additional text to option 2 (in bold):

*<sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein glucose polymers **that consist of D-glucose units linked primarily by  $\alpha$ -1-4 bonds and that have a dextrose equivalent (D.E.) of less than 15** should be the preferred carbohydrates used.*

*Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.*

The justification provided for the additional text was that a maximum DE value that approximates the sweetness level of lactose provides a safeguard against overly sweet tasting products.

One member country was of the view that the sentence as presented in [REP18/NFSDU Appendix II](#) "For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred" could be retained as a principle and that in the future, should there be more science available to evaluate the intensity of sweetness, it can be further specified in the standard.

## Conclusion

Compositional requirements in a standard should be science based and enforceable.

As outlined in the consultation paper, there is no direct link with the DE value of a carbohydrate and its relative sweetness. Relative sweetness in itself is not an absolute analytical measure. The previous wording referring to 'sweet taste of carbohydrate sources' was considered not to be enforceable as 'sweetness' would be difficult to objectively measure and a DE limit for carbohydrate sources was suggested as an alternative. However, the DE value of carbohydrate ingredients cannot be measured in the final product, making a DE limit difficult to enforce.

The eWG views were split between the two options presented in the consultation paper. While the eWG was not directly asked for a view on whether to include a DE limit or not, based on the responses received there appears to be very limited support for its inclusion as a criteria in footnote 4 for carbohydrate sources in [name of product] for young children not based on milk protein.

Footnote 4 has been extensively discussed in previous eWGs and Committee meetings. It is the only compositional requirement still outstanding.

The Chair recommends that the Committee considers; taking into account the already agreed restrictions and prohibitions in footnote 4, whether there is a need to specify that glucose polymers are the preferred carbohydrates for products not based on milk protein, and whether this contributes to the aim of limiting the sweetness of [name of product] for young children not based on milk protein.

It is the recommendation of the Chair that the following text is adopted and the Committee consider whether the text in square brackets adds extra value:

<b>Recommendation 1</b>
That CCFSDU agree to the following text:  <i><sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. <b>[For products not based on milk protein glucose polymers should be the preferred carbohydrates used.]</b></i>

*Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.*

## 2 SENTENCE IN SECTION 3.2.1 FOR [NAME OF PRODUCT] FOR YOUNG CHILDREN

At CCNFSDU40 it was noted that ([REP19/NFSDU](#) para 26): *sweeteners, although not permitted in these products, together with flavourings should be addressed in the section on food additives. For the non-carbohydrate ingredients not considered food additives or flavourings, a proposal was made that they could be better addressed in the section on optional ingredients*". It was agreed that the last part of footnote 4, referring to the types of non-carbohydrate ingredients that should not be added to [name of product] for young children with the purpose of imparting or enhancing a sweet taste, be transferred to section 3.2.1 on Optional ingredients and kept in square brackets for further consideration. The current drafting of 3.2.1 is ([REP19/NFSDU](#) Appendix II):

### 3.2 Optional Ingredients

*3.2.1 In addition to the compositional requirements listed under 3.1.3 Section B, other ingredients, or substances may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted. **[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]].** (For consideration by EWG on follow-up formula)*

The consultation paper noted that in addition to sweeteners not being permitted in [name of product] for young children, the addition of flavourings is managed through the flavouring provisions and not through optional ingredients.

### EWG views

The eWG was asked whether they were 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. The majority of respondents were not aware of such substances or ingredients. The substances or ingredients that were identified were: numerous D isomers of amino acids (specific ones were not identified); numerous non-available or partially available carbohydrates (specific ones were not identified); ingredients that impart a sweet taste that may not necessarily be classified as food additives, such as those that contain non-carbohydrate substances (e.g. Stevia rebaudiana); or those that in themselves do not impart taste sweet but are taste modifiers (e.g. Synsepalum dulcificum containing the glycoprotein Miraculin). The respondents that identified the above mentioned substances (1 CM, 1 CMO) were not aware of these ingredients currently being used and did not comment on whether it would be feasible to add them to [name of product] for young children.

The Chair notes that the consultation paper did not ask respondents to comment on whether the sentence should be retained or deleted. Some respondents, however, provided their view on this. Despite the lack of currently available substances or ingredients that could be added to impart or enhance sweet taste, the need to future proof the Standard taking into account possible future technological innovations and the current momentum to develop non-sugar ingredients that impart or enhance a sweet taste was highlighted by some respondents (1 CM, 1 CMO). Additionally one respondent suggested the retention of the sentence but did not provide a justification for their view.

Some respondents (1 CM, 2 CO) noted that the optional ingredient provisions are for substances and ingredients added for particular nutritional purposes and that 'imparting or enhancing a sweet taste' is not a nutritional purpose and that the sentence should be deleted. Another reason for deletion of the sentence mentioned by respondents (2 CO) was that there is no definition or standardized method of analysis for measuring sweet taste and therefore sweet taste is not an enforceable concept.

### Conclusion

The responses received from the eWG did not identify any current substances or ingredients that could be added to [name of product] for young children with the purpose of imparting or enhancing a sweet taste; and that would otherwise be permitted in the Standard. The Chair notes that the Optional ingredient provisions are intended for substances and ingredients added for particular nutritional purposes and that imparting or enhancing a sweet taste cannot be considered a nutritional purpose.

However, given the highlighted need to future proof the Standard, the Chair recommends that the Committee considers whether the sentence should be retained under *Optional Ingredients* to capture the intent that no

such substances or ingredients should be added to these products should they become available in the future, or whether it be deleted.

#### Recommendation 2

That CCNFSDU considers whether the sentence *[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]]* should be retained under 3.2.1 Optional ingredients to capture the intent that no such substances or ingredients should be added to these products or be deleted.

### 3 REMAINING SECTIONS OF THE STANDARD

Additional sections that are included within the Infant Formula Standard and/or the current Follow-up Formula Standard and which were addressed as part of the 2019 eWG consultation included:

- purity requirements
- vitamin compound and mineral salts
- consistency and particle size
- specific prohibitions
- food additives
- contaminants
- hygiene
- packaging
- fill of container
- methods of analysis and sampling.

As a starting point for discussions, the eWG considered whether the current provisions for the above sections contained within the Infant Formula Standard ([CXS 72-1981](#) (Revised 2007)), the current Follow-up Formula Standard ([CXS 156-1987](#)), and any other relevant Codex standards applicable to foods for older infants and young children (namely the Standard for Canned Baby Foods ([CXS 73-1981](#)), and Standard for Processed Cereal-Based Foods for Infants and Young Children ([CXS 74-1981](#) (Revised 2006)) could be adopted or modified for follow-up formula for older infants and [name of product] for young children.

#### 3.1 PURITY REQUIREMENTS

The purity requirement provisions in the current Follow-up Formula Standard are identical to those in the Infant Formula Standard with the exception of the age range, and are very similar to provisions in the Standard for Canned Baby Foods and the Standard for Processed Cereal-based Foods for Infants and Young Children where relevant. They read as follows;

#### 3.4 Purity requirements

##### 3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

The eWG was asked if they agreed with the proposal to retain the provision for purity requirements as presented in the current Follow-up Formula Standard for both follow-up formula for older infants and for [name of product] for young children, noting the need for modification and separation of the relevant age ranges depending on the final structure of the standard(s).

#### EWG views

There was unanimous support from the eWG for the proposed approach for both product categories.

#### Conclusion

As it was the preference of all eWG respondents to adopt this approach, it is the proposal of the Chair that the below recommendation be agreed to by the Committee noting the need for modification and separation of the relevant age ranges depending on the final structure of the standard(s).

<b>Recommendation 3</b>
<p><b>a) Follow-up formula for older infants:</b> That CCNFSDU agree to the following text for 'Purity Requirements' for follow-up formula for older infants;</p> <p>All ingredients shall be clean, of good quality, safe and suitable for ingestion by <b>[older] infants from the 6th month on and young children</b>. They shall conform with their normal quality requirements, such as colour, flavour and odour.</p>
<p><b>b) [Name of product] for young children:</b> That CCNFSDU agree to the following text for 'Purity Requirements' for [name of product] for young children;</p> <p>All ingredients shall be clean, of good quality, safe and suitable for ingestion by <b>infants from the 6th month on and</b> young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.</p>

### 3.2 VITAMIN COMPOUNDS AND MINERAL SALTS

Section 3.4.2.1 relating to the Vitamin Compounds and Mineral Salts provisions in the current Follow-up Formula Standard is essentially identical to that in the Infant Formula Standard (section 3.4), *Standard for Canned Baby Foods* (section 3.1.2.1) and the *Standard for Processed Cereal-based Foods for Infants and Young Children* (section 3.7.4). The current Follow-up Formula Standard (section 3.4.2.2) and the *Standard for Canned Baby Foods* (section 3.1.2.2) both have an additional provision relating to sodium. Whilst there is a minimum and maximum level for sodium set for follow-up formula for older infants, levels have not been set for [name of product] for young children. The current provision reads as follows;

<p><b>3.4.2 Vitamin compounds and mineral salts</b></p> <p><b>3.4.2.1</b> Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the <a href="#">Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children</a> approved by the Codex Alimentarius Commission (CAC/GL 10-1979).</p> <p><b>3.4.2.2</b> The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6</p>
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The eWG was asked if they agreed with the proposal to retain provision 3.4.2.1 in the current Follow-up Formula Standard for both follow-up formula for older infants and [name of product] for young children, and retain provision 3.4.2.2 for follow-up formula for older infants only, as it is not relevant to [name of product] for young children. There is no limit set for [name of product] for young children, but there is a prohibition on the addition of sodium chloride.

#### EWG views

##### *Follow-up formula for older infants*

There was majority support for the proposal as presented for follow-up formula for older infants (20 CM, 1 CMO, 2 CO). It was however suggested by 1 CMO that with respect to the exact text for 3.4.2.1, provision 3.4 of the more recently revised Infant Formula Standard could be adopted for follow-up formula for older infants. Several comments (3 CM, 1 CO) relating to provision 3.4.2.2 for follow-up formula for older infants were received. The comment was made by 2 CM and 1 CO that provision 3.4.2.2 was not considered necessary as it was considered inherent that sodium from vitamin compounds and mineral salts should be within the maximum limit for sodium in the product. Two respondents commented that the maximum limit for sodium takes into account naturally occurring sodium and that derived from sodium containing ingredients, with one CM proposing the following amended text for 3.4.2.2;

*The total sodium content (taking into account natural occurring sodium and the sodium derived from vitamin and mineral ingredients) shall be within the limit for sodium in Section 3.2.6.*

##### *[Name of product] for young children*

There was majority support for the proposal as presented for [name of product] for young children (17 CM, 1 CMO, 2 CO). It was however suggested by 1 CMO that with respect to the exact text for 3.4.2.1, provision 3.4 of the more recently revised Infant Formula Standard could be adopted for [name of product] for young children. Two CM and 1 CO supported retaining both 3.4.2.1 and 3.4.2.2 provisions for [name of product] for young

children. Three CM and 1 CO were of the view that a maximum sodium limit should be included in the Standard for [name of product] for young children. One CM suggested amended text for 3.4.2.2 (as presented above for follow-up formula for older infants).

### Conclusion

As there was majority support for retaining both provision 3.4.2.1 and 3.4.2.2 of the current Follow-up Formula Standard, it is the recommendation of the Chair that both provisions be adopted for follow-up formula for older infants without modification.

As there was majority support for retaining only provision 3.4.2.1 of the current Follow-up Formula Standard for [name of product] for young children, it is the recommendation of the Chair that this provision be adopted, and that provision 3.4.2.2 be deleted. At CCNFSDU38, the Committee agreed not to set levels for sodium for [name of product] for young children. The current draft Standard includes a prohibition; *Sodium chloride should not be added to [name of product] for young children*. It is therefore recommended that this discussion not be reopened.

<b>Recommendation 4</b>
<p><b>a) Follow-up formula for older infants:</b> That CCNFSDU agree to the following text for 'Vitamin Compounds and Mineral Salts' for follow-up formula for older infants;</p> <p><b>Vitamin compounds and mineral salts</b></p> <p>Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the <a href="#">Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children</a> approved by the Codex Alimentarius Commission (CXG 10-1979).</p> <p>The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.1.</p>
<p><b>b) [Name of product] for young children:</b> That CCNFSDU agree to the following text for 'Vitamin Compounds and Mineral Salts' for [name of product] for young children;</p> <p><b>Vitamin compounds and mineral salts</b></p> <p>Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the <a href="#">Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children</a> approved by the Codex Alimentarius Commission (CXG 10-1979).</p> <p><b>The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6</b></p>

### 3.3 CONSISTENCY AND PARTICLE SIZE

Whilst the Standard for Canned Baby Foods, and the Standard for Processed Cereal-Based Foods for Infants and Young Children both contain requirements for consistency and particle size, the Infant Formula Standard and the current Follow-up Formula Standard provisions relate to products that when prepared are in a liquid rather than solid form. The current provision within the Follow-up Formula Standard reads as follows:

<p><b>3.5 Consistency and particle size</b> When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.</p>
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The eWG was asked if they supported the proposal to retain provision 3.5 in the current Follow-up Formula Standard relating to consistency and particle size for both follow-up formula for older infants and for [name of product] for young children.

### EWG views

There was unanimous support from the eWG for this approach for both product categories (21 CM, 1 CMO, 2 CO), with no respondents disagreeing with the proposal. One CMO and 1 CM suggested that the provision be amended to include the applicable age range; i.e. that is to say that 'When prepared according to the directions

of use, the product shall be free of lumps and of large, coarse particles *and suitable for adequate feeding of [older infants] or [young children]*’.

### Conclusion

As there was majority support for retaining provision 3.5 relating to ‘Consistency and Particle Size’ of the current Follow-up Formula Standard, it is the recommendation of the Chair that the Committee agree to adopt the text for follow-up formula for older infants and [name of product] without modification.

<b>Recommendation 5</b>
<p><b>a) Follow-up formula for older infants:</b></p> <p>That CCNFSDU agree to the following text for ‘Consistency and Particle Size’ for follow-up formula for older infants;</p> <p><b>Consistency and particle size</b></p> <p>When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.</p>
<p><b>b) [Name of product] for young children:</b></p> <p>That CCNFSDU agree to the following text for ‘Consistency and Particle Size’ for [name of product] for young children;</p> <p><b>Consistency and particle size</b></p> <p>When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.</p>

### 3.4 SPECIFIC PROHIBITIONS

All four standards assessed by the eWG include a provision that states; *The product and its component shall not have been treated by ionizing radiation/irradiation*. The *Standard for Processed Cereal-based Foods for Infants and Young Children* includes an additional statement that says; *The use of partially hydrogenated fats for these products is prohibited*.

As the draft essential compositional requirements for both follow-up formula for older infants and for [name of product] for young children include a statement that; *Partially hydrogenated oils and fats shall not be used*, it was deemed unnecessary to duplicate this statement in the Specific Prohibitions for the respective products.

The current provision within the Follow-up Formula Standard read as follows:

<p><b>3.6 Specific prohibitions</b></p> <p>The product and its components shall not have been treated by ionizing radiation.</p>
--

The eWG was asked if they supported the proposal to retain the Specific Prohibition provision within the current Follow-up Formula Standard, and the statement; *The product and its component shall not have been treated by ionizing radiation*, for both follow-up formula for older infants and [name of product] for young children.

### EWG views

There was unanimous support from the eWG for this approach with 21 CM, 1 CMO and 2 CO supporting adoption of the text in the current Follow-up Formula Standard for both follow-up formula for older infants and for [name of product] for young children.

### Conclusion

As there was majority support for retaining provision 3.6 relating to ‘Specific Prohibitions’ of the current Follow-up Formula Standard, it is the recommendation of the Chair that the Committee agree to adopt the text for follow-up formula for older infants and [name of product] without modification. A statement on partially hydrogenated oils and fats is included within the essential composition section of the draft standard (for the respective products) and therefore need not be duplicated within this provision.

Recommendation 6
<p><b>a) Follow-up formula for older infants:</b></p> <p>That CCNFSDU agree to the following text for 'Specific Prohibitions' for follow-up formula for older infants;</p> <p><b>Specific prohibitions</b></p> <p>The product and its components shall not have been treated by ionizing radiation.</p>
<p><b>b) [Name of product] for young children:</b></p> <p>That CCNFSDU agree to the following text for 'Specific Prohibitions' for [name of product] for young children;</p> <p><b>Specific prohibitions</b></p> <p>The product and its components shall not have been treated by ionizing radiation.</p>

### 3.5 FOOD ADDITIVES (EXCLUDING FLAVOURINGS)

As a starting point for discussions on food additives, rules to guide this work were developed. The three rules presented for eWG consideration are summarised below.

1) Conformity to the basic principles for the use of food additives as laid out in the Preamble to GSFA ([CXS 192-1995](#)) which include:

- 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 in the revised Standard(s) for Follow-up Formula for older infants and [name of product] for young children.
- ii) **Technological justification:** The use of the food additive is justified for use in this commodity group as per the requirements in section 3.2 of the Preamble to the GSFA (CXS 192-1995).
- iii) **Specification for identity and purity:** Food additives should be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies.

2) Alignment of food additives in CCNFSDU Standards with the GSFA

- As this is a separate piece of work, alignment will not be completed as part of the review of this Standard.

3) Framework for considering technological justification

- As work on this is ongoing, additives currently approved in this Standard do not need to be re-evaluated under the framework.

The alignment of the Follow-up Formula Standard with the GSFA is planned for 2021. This will involve harmonising the food additive permissions between the revised Follow-up Formula Standard and the GSFA. Changes to any additive permissions that are necessary for alignment across the CCNFSDU commodity standards will occur at this time. In light of this, the eWG was asked to comment on the proposal that the current permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard be retained for follow-up formula for older infants and [name of product] for young children.

The consultation paper additionally recommended that administrative changes, consistent with the changes made during the revision of the Infant Formula Standard and *Standard for Processed Cereal-Based Foods for Infants and Young Children*, are made to the current list of food additives (see Conclusion on administrative changes section below).

### EWG views

#### **Rules to guide the work**

There was unanimous agreement among respondents (21CM, 1 CMO, 2 CO) to the rules for follow-up formula for older infants. Two eWG members (1 CM, 1 CO) commented that as the first rule "Conformity to basic principles in the GSFA" sub-part i) Safety is written in the consultation paper, it "*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.”*

For [name of product] for young children the majority of respondents (20 CM, 1 CMO, 3 CO) agreed to the rules. One CM did not agree to the rules due to concern relating to the first rule sub part i) Safety. The CM mentioned they do not believe that there should be a requirement that JECFA specifically evaluate the use of an additive in a food intended for consumption by young children.

The Chair would like to clarify that the intention of the first rule is conformity to the GSFA and not to change the intent or meaning of Section 3.1 of the Preamble to the GSFA. While all currently permitted additives have been evaluated by JECFA, the evaluations have not been done for specifically for use in follow-up formula. The consultation paper aimed to describe the text in the GSFA as it applies to follow-up formula for older infants and [name of product] for young children, with older infants or young children being the ‘consumers’ that the GSFA text refers to. The Chair would like to also further clarify that the intention is for the rules to guide the work of the eWG, and that the rules will not be presented as part of the Standard(s).

Section 3.1 of the Preamble to the GSFA is replicated below.

#### *“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.*

*b) The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g. diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers.*

*c) The quantity of an additive added to food is at or below the maximum use level and is the lowest level necessary to achieve the intended technical effect. The maximum use level may be based on the application of the procedures of Annex A, the intake assessment of Codex members or upon a request by the CCFA to JECFA for an independent evaluation of national intake assessments.”*

#### **Permissions for food additives**

The eWG unanimously agreed (21 CM, 1 CMO, 3 CO) to retain the current permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard for both follow-up formula for older infants and [name of product] for young children. One CM stated that their agreement is provisional to *JECFA having evaluated the additives and considered their uses in follow-up formula for older infants to be consumed by infants as acceptable, and in the case of young children that there are no updates or revisions to JECFA’s evaluations and therefore no new concerns regarding the exposure of the additives in young children.*

One CMO noted that ‘Packaging gases’ is a functional class recognised in the EU and at Codex level, and as such nitrogen and carbon dioxide should be listed under that functional class within the Food Additive section as is the approach in the Infant Formula Standard. They noted that this could also be addressed during the alignment. At the moment packaging gases are under Section 7 Packaging in the current Follow-up Formula Standard. In the Infant Formula Standard they are under both Section 4 Food Additives and Section 7 Packaging.

#### **Administrative changes**

There was also general agreement (21 CM, 1 CMO, 3 CO) to the administrative changes proposed in the consultation paper. Further proposals included that in addition, where necessary, the names of the additives be revised to conform to the official Codex name of the additive as listed in *Class Names and the International Numbering System for Food Additives (CXG 36-1989)*; and that the Committee may consider referencing the additive provisions in the appropriate food category in the GSFA, rather than including the table, once the alignment work is completed.

#### **Conclusion on Food additives**

Based on the support from the eWG it is the recommendation of the Chair that the current permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard are retained for both follow-up formula for older infants and [name of product] for young children. This will assist in a timely completion of the review of the Follow-up Formula Standard.

The Chair also notes that following the completion of the alignment with the GSFA, the permissions in the Standard(s) for Follow-up Formula will be replaced by a reference to the corresponding sections of the GSFA<sup>3</sup>.

### Conclusion on administrative changes

Based on the support of the eWG, the Chair recommends that the Committee agree to the following administrative changes:

- i) Edit the names of the following functional classes to make them consistent with the terms used in the GSFA (CXS 192-1995):

Current names in Standard for Follow-up Formula (CXS 156-1987)	Proposed new names in General Standard for Food Additives (CXS 192-1995)
4.1 Thickening Agents	Thickener
4.2 Emulsifiers	Emulsifier
4.3 pH-Adjusting Agents	Acidity Regulator
4.4 Antioxidants	Antioxidant

- ii) Addition of International Number System identifiers (INS)
- iii) Tabulate the permissions for ease of use

Further to aligning the names of the functional classes of food additives with those used in the GSFA, the Chair proposes to also align the names of the following food additives:

Current names in Standard for Follow-up Formula (CXS 156-1987)	Proposed new names in General Standard for Food Additives (CXS 192-1995)
Locust bean gum	Carob bean gum
Sodium citrate	Trisodium citrate; Sodium dihydrogen citrate
Potassium citrate	Tripotassium citrate; Potassium dihydrogen citrate
L-ascorbic acid and its Na, Ca salts	Ascorbic acid, L-; Sodium ascorbate; Calcium ascorbate

This alignment of food additive names is in line with the Infant Formula Standard.

The Chair further notes that CCNFSDU has agreed to include the permission to add L(+) lactic acid producing cultures to follow-up formula for older infants in the optional ingredients section 3.2 as per the approach in the Infant Formula Standard during its revision. This is due to the fact that bacterial cultures are not considered food additives by Codex and are not included within the GSFA. As a consequential amendment, the Chair has now removed the permission for L(+) lactic acid producing cultures from the food additive permissions. Additionally a footnote has been added to indicate that the note which is included in the current Follow-up Formula Standard: *'within the limits for sodium in Section 3.2.6'* is applicable to follow-up formula for older infants only as it is not relevant for [name of product] for young children due to there not being set levels for sodium. The section number 3.2.6 has also been corrected to 3.1.

The Chair has prepared a draft of Section 4 Food additives which incorporates the above administrative changes (see APPENDIX II: SECTION 4 FOOD ADDITIVES).

The Chair notes that the administrative change proposal *iv) to move the permissions for packaging gases (i.e. carbon dioxide and nitrogen) from Section 7 Packaging to Section 4 Food Additives* is in conflict with the proposal to retain the packaging provisions in the current Follow-up Formula Standard for both follow-up formula for older infants and for [name of product] for young children (see consultation paper section 4.2.9 and section 3.9 of this paper).

The Chair therefore additionally recommends that the Committee consider if 'Packaging Gases' should also be included in the Food Additive section and listed under the appropriate functional class, as per the approach taken in the Infant Formula Standard. The Chair notes there was majority support from the eWG for retaining

<sup>3</sup> [CCFA guidance document, Attachment 1](#)

the Packaging provisions within the current Follow-up Formula Standard (see section 3.9 and Recommendation 13)

<b>Recommendation 7</b>
<p><b>a) Follow-up formula for older infants:</b></p> <p>That CCNFSDU agree to retain the permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard (CXS 156-1987), for follow-up formula for older infants, noting these will be replaced by a reference to the corresponding sections of the GSFA following the completion of the alignment work.</p>
<p><b>b) [Name of product] for young children:</b></p> <p>That CCNFSDU agree to retain the permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard (CXS 156-1987), for [name of product] for young children, noting these will be replaced by a reference to the corresponding sections of the GSFA following the completion of the alignment work.</p>

<b>Recommendation 8</b>
<p><b>a)</b> That CCNFSDU agree to administrative changes i – iii, and to aligning the names of food additives in the current Follow-up Formula Standard with those in the GSFA (see Appendix II for administrative changes)</p>
<p><b>b)</b> That CCNFSDU consider if ‘Packaging gases’ should be included in the Food Additive section and listed under the appropriate functional class, noting also <b>Recommendation 13</b> to retain them in Section 7 Packaging.</p>

### 3.5.1 Carry-over of food additives and nutrient carriers

Two options were presented for the eWG to consider that address the carry-over of food additives and nutrient carriers. The options were based on the existing provisions for carry-over of food additives and nutrient carriers contained in the Codex standards applicable to foods for older infants and young children:

**Option 1:** Maintain status quo: referencing Section 4.1 of the GSFA ([CXS 192-1995](#))

**Option 2:** Adopt text from the Infant Formula Standard and the Standard for Processed Cereal-based Foods for Infants and Young Children

The Chair notes that it appears that the current Follow-up Formula Standard incorrectly references Section 4.1 of the GSFA and that Section 4.3 of the GSFA explicitly mentions follow-up formulae:

#### **4.3 Foods for Which the Carry-over of Food Additives is Unacceptable**

*Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.*

- a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.
- b) 13.2 - Complementary foods for infants and young children.

### **EWG views**

#### *Follow-up formula for older infants*

Two respondents (1 CM, 1 CO) supported Option 1 for follow-up formula for older infants and 20 respondents (17 CM, 1 CMO, 2 CO) supported Option 2. Three CMs did not support either of the options. Several eWG members questioned the accuracy of status quo referring to Section 4.1 of the GSFA.

Those in support of Option 2 considered it would improve clarity; provide consistency across Codex standards; is in line with the intent of Section 4.3 of the GSFA; and the same requirements that apply to infant formula should also apply to follow-up formula for older infants. The option of inserting a reference to the Section 4.3 of the GSFA was also mentioned as an alternative by a CMO who supported Option 2.

One CM not in support of either option considered that the text in the Infant Formula Standard and the Standard for Processed Cereal-based foods for Infants and Young Children is not in accordance with the requirements set out in the Preamble of the GSFA. They proposed that a general reference to the GSFA is continued but that it should include all of Section 4. This was also a proposal by a CO supporting option 1. Two CMs not in support of either option recommended referencing Section 4.3 of the GSFA.

*[Name of product] for young children*

For *[name of product] for young children* Option 1 was supported by four respondents (3 CM, 1 CO) and Option 2 by 16 respondents (15 CM, 1 CMO, 2 CO) and 3 CMs did not support either of the options. The justifications given were similar for *[name of product] for young children* than those for follow-up formula for older infants.

**Conclusion**

The Chair notes the support from the eWG to adopt the text from the Infant Formula Standard and the *Standard for Processed Cereal-based foods for Infants and Young Children* for both follow-up formula for older infants and *[name of product] for young children*.

However, given the incorrect reference to Section 4.1 of the GSFA in the current Follow-up Formula Standard, the Chair recommends that the Committee consider an additional option to reference the entire Section 4 of the Preamble of the GSFA. This proposal would ensure that Section 4.3 which specifically mentions follow-up formulae is read in the context the entire Section 4 provides. Referencing the GSFA would follow the principle to reference existing Codex texts rather than repeat requirements in commodity standards.

**Option 1:** Insert a reference to Section 4 of the Preamble of the GSFA ([CXS 192-1995](#))

**Option 2:** Adopt the text from the Infant Formula Standards and the *Standard for Processed Cereal-based foods for Infants and Young Children* for the carry-over of food additives and nutrient carriers:

*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 (CXG 10-1979) may be present in the foods described in [section 2.1 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 (CXS 192-1995).*

<b>Recommendation 9</b>	
<b>a) Follow-up formula for older infants:</b>	
Please indicate your preference of the two options and provide justification for your response	
<b>Option 1:</b> reference Section 4 of the Preamble of the GSFA ( <a href="#">CXS 192-1995</a> )	<b>Option 2:</b> Adopt the text from the Infant Formula Standards and the Standard for Processed Cereal-based foods for Infants and Young Children for the carry-over of food additives and nutrient carriers.
<b>Response:</b>	
<b>b) [Name of product] for young children:</b>	
Please indicate your preference of the two options and provide justification for your response	
<b>Option 1:</b> reference Section 4 of the Preamble of the GSFA ( <a href="#">CXS 192-1995</a> )	<b>Option 2:</b> Adopt the text from the Infant Formula Standards and the Standard for Processed Cereal-based foods for Infants and Young Children for the carry-over of food additives and nutrient carriers.
<b>Response:</b>	

### 3.6 FLAVOURINGS

Flavourings currently allowed in the Follow-up Formula Standard include natural fruit extracts, vanilla extract, ethyl vanillin and vanillin. These flavourings are in line with flavourings permitted in products intended for the same age range:

**4.5 Flavourings**  
Natural Fruit Extracts: GMP  
Vanilla extract: GMP  
Ethyl vanillin: 5 mg/100 ml  
Vanillin: 5 mg/ 100 ml

The flavourings are placed under section 4 on Food additives in the current Follow-up Formula Standard. As the GSFA does not cover flavourings, they will not be considered as a part of the planned alignment of Follow-up Formula Standard (CXS 156-1987) with the GFSA. The placement of the provisions for flavourings should be discussed at a later date following the completion of the alignment work.

#### EWG views

EWG members were asked to consider the proposal that the provisions for flavourings contained within the current Follow-up Formula Standard be retained for both follow-up formula for older infants and [name of product] for young children.

One respondent noted that, as specified in the [Codex Procedural Manual](#), the following text should be inserted in the standard: “*The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)*”.

#### *Follow-up formula for older infants*

The respondents in favour of retaining the permitted flavourings for follow-up formula for older infants (11 CM, 4 CO) stated that there are no safety concerns at the permitted levels; that the list is very limited; other foods for the same age group are permitted to contain similar flavourings; and the flavourings are used primarily for the purpose to improve palatability. One CM in favour of retaining the provisions mentioned that their support is provisional to JECFA having evaluated the flavours. In addition to those that supported retaining the flavouring provisions as is, one CM proposed that the provisions for flavourings should align with the Standard for Processed Cereal-based Foods for Infants and Young Children that allows the use of the same flavourings but some at slightly higher levels. One CMO agreed in general to retain the provisions but suggested that in addition to the name of the flavouring substance, the inclusion of their JECFA number as the JECFA numbers for flavouring substances are essentially equivalent to the INS numbers for food additives and indicate that there are JECFA evaluations and specifications for them.

Those of the view that the current provisions should not be retained (6 CM) mentioned that since the Infant Formula Standard does not contain any provisions for flavourings, as such no flavourings should be allowed in follow-up formula for older infants which has been agreed to be a breastmilk substitute. It was noted that the compositional differences to infant formula are minor, thus there should be no reason for the addition of flavourings to follow-up formula for older infants for palatability reasons. One CM suggested that only vanilla extract and vanillin should be allowed.

#### *[Name of product] for young children*

The majority (18 CM, 4 CO) supported the retention of the current provisions for flavourings for [name of product] for young children, one CM provisional to JECFA having evaluated the flavours. Additionally to those that supported the retention of the provision as is, as for follow-up formula for older infants, it was proposed by some respondents that the provisions for flavourings should align with the Standard for Processed Cereal-based Foods for Infants and Young Children that allows the use of same flavourings; and that in addition to the name the JECFA numbers should be included for the flavouring substances.

The justifications given included that for young children each flavouring has a JECFA safety assessment, young children consume other foods with flavourings, only a limited number of flavourings are permitted; their primary use is to improve palatability; and that [name of product] for young children is not considered a breastmilk substitute.

## Conclusion

Based on the responses received, the Chair recommends that the current provisions for flavourings be retained for both follow-up formula for older infants and [name of product] for young children.

The Chair also recommends that the following text should be inserted in the standard(s): *“The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)”* in accordance with the Codex Procedural Manual and that the JECFA numbers be included in addition to the name of the flavouring substances.

The Chair reiterates that consideration should be given to the placement of the provisions for flavourings at a later date following the completion of the alignment work.

Recommendation 10
<p><b>a) Follow-up formula for older infants:</b></p> <p>That CCNFSDU agree to the following text for follow-up formula for older infants:</p> <p><b>4.5 Flavourings</b></p> <p>Natural Fruit Extracts: GMP</p> <p>Vanilla extract: GMP</p> <p>Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml</p> <p>Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml</p> <p><b><i>[The flavourings used in products covered by this standard should comply with the <a href="#">Guidelines for the Use of Flavourings (CXG 66-2008)</a>]</i></b></p>
<p><b>b) [Name of product] for young children:</b></p> <p>That CCNFSDU agree to the following text for [name of product] for young children:</p> <p><b>4.5 Flavourings</b></p> <p>Natural Fruit Extracts: GMP</p> <p>Vanilla extract: GMP</p> <p>Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml</p> <p>Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml</p> <p><b><i>[The flavourings used in products covered by this standard should comply with the <a href="#">Guidelines for the Use of Flavourings (CXG 66-2008)</a>]</i></b></p>

### 3.7 CONTAMINANTS

The current Follow-up Formula Standard does not reference the General Standard for Contaminants and Toxins in Food and Feed ([CXS 193-1995](#)) whereas the more recently revised Infant Formula Standard does. Furthermore, the Infant Formula Standard also states that the products covered by the Standard ‘*shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission*’.

Given the Infant Formula Standard has undergone a more recent review, the eWG was asked if they supported the proposal to adopt the Contaminant provision within this Standard for both follow-up formula for older infants, and for [name of product] for young children. The provision reads as follows:

<p><b>5. CONTAMINANTS</b></p> <p>The products covered by this Standard shall comply with the Maximum levels of the <a href="#">General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)</a>.</p> <p>The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.</p>
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## EWG views

There was majority support from the eWG (20 CM, 1 CMO, 3 CO) for the proposal to adopt the Contaminant provision within the more recently revised Infant Formula Standard for both follow-up formula for older infants, and for [name of product] for young children.

## Conclusion

As there was majority support for adopting the 'Contaminant' provision within the Infant Formula Standard, it is the recommendation of the Chair that the Committee agree to adopt the text as drafted for follow-up formula for older infants and [name of product] without modification.

Recommendation 11
<p><b>a) Follow-up formula for older infants:</b> That CCNFSDU agree to the following text for 'Contaminants' for follow-up formula for older infants;</p> <p><b>CONTAMINANTS</b></p> <p>The products covered by this Standard shall comply with the Maximum levels of the <a href="#">General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995)</a>.</p> <p>The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.</p>
<p><b>b) [Name of product] for young children:</b> That CCNFSDU agree to the following text for 'Contaminants' for [name of product] for young children;</p> <p><b>CONTAMINANTS</b></p> <p>The products covered by this Standard shall comply with the Maximum levels of the <a href="#">General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995)</a>.</p> <p>The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.</p>

## 3.8 HYGIENE

It is worth noting that the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CXC 66-2008\)](#) covers:

*'the production, preparation and use of products available in powdered form, referred to as Powdered Formulae (PF) for the purpose of this document, and specifically manufactured to be used for infants and young children either as a breast milk substitute, to supplement infant formula or fortify human milk or in combination with other foods as part of the weaning diet for older infants and young children.*

*Products included are infant formulae, follow-up formulae, formulae for special medical purposes intended for infants and which serve as the sole source of nutrition, human milk fortifiers and powdered formulae for special medical purposes for infants and young children intended to partially replace or supplement breast milk, infant formulae or follow-up formulae'.*

It is also important to note that preparation, storage and use instructions are covered within Section 9.5 – Information for Use (of the respective labelling provisions) in the draft revised Standard for follow-up formula for older infants and [name of product] for young children.

The eWG was asked if they supported the Chair's proposal; to adopt the 'Hygiene' provisions contained within the more recently revised Infant Formula Standard for both follow-up formula for older infants and for [name of product] for young children. Noting that agreement has already been reached by the Committee on Section 9.5 – Information for Use for follow-up formula for older infants, the Chair recommended that additional provisions not be included within the Hygiene section, and that a general reference to the General Principles of Food Hygiene (CXC 1- 1969), Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008), and the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997) is appropriate for both product categories. The relevant provision from the Infant Formula Standard reads as follows;

## 6. HYGIENE

**6.1** It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the [General Principles of Food Hygiene \(CAC/RCP 1- 1969\)](#), and other relevant Codex texts such as the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CAC/RCP 66-2008\)](#).

**6.2** The products should comply with any microbiological criteria established in accordance with the [Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods \(CAC/GL 21-1997\)](#).

### EWG views

From the eWG responses, there was majority support for the proposal presented by the Chair. There were 21 CM, 1 CMO, 3 CO who agreed to the recommendation to adopt provisions 6.1 and 6.2 from the Infant Formula Standard relating to hygiene for both follow-up formula for older infants and [name of product] for young children. Two of the 21 CM's in favour, provided further comments. One CM recommended that two additional Codex documents should be referenced to cover liquid formula that have been commercially sterilised, notably the [Codex Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CAC/RCP 40-1993\)](#) and the [Codex Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CAC/RCP 23-1979\)](#). A further comment was received from one CM expressing their concern regarding the FAO/WHO guidance to use boiled water that has been cooled to no less than 70 degrees for the preparation of powdered infant formula (FAO/WHO 2007), primarily due to concerns relating to risk of oral burns.

### Conclusion

As there was majority support for adopting the 'Hygiene' provisions within the Infant Formula Standard, it is the recommendation of the Chair that the Committee agree to adopt the text as drafted for follow-up formula for older infants and [name of product] for young children. The Chair also recommends that the Committee consider if it is appropriate to reference [Codex Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CXC 40-1993\)](#) and the [Codex Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CXC 23-1979\)](#) in addition to the other Codex documents noting that the reference to all documents in this provision states; '*prepared and handled in accordance with the appropriate sections*'. The Chair recommends that the Committee discuss and consider whether ready-to-feed follow-up formula is currently produced and packaged in cans, if not, should the Codex Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods be referenced in this section to future proof for alternative, or new packaging mediums?

With regards to water temperature, the Chair notes that the Committee has already considered this when agreeing to the Information for Use (Section 9.5) labelling provisions for follow-up formula for older infants which states that *product 'must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice'*. This discussion will therefore not be reopened.

### Recommendation 12

#### a) Follow-up formula for older infants:

That CCNFSDU agree to the following text for 'Hygiene' and consider whether the additional references in [ ] are necessary for follow-up formula for older infants;

#### HYGIENE

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the [General Principles of Food Hygiene \(CXC 1- 1969\)](#), and other relevant Codex texts such as the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CXC 66-2008\)](#)

[the [Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CXC 40-1993\)](#) and the [Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CXC 23-1979\)](#) ]

The products should comply with any microbiological criteria established in accordance with the [Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods \(CXC 21-1997\)](#).

**b) [Name of product] for young children:**

That CCNFSDU agree to the following text for 'Hygiene' and consider whether the additional references in [ ] are necessary for [name of product] for young children;

**HYGIENE**

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the [General Principles of Food Hygiene \(CXC 1- 1969\)](#), and other relevant Codex texts such as the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CXC 66-2008\)](#)

[the [Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CXC 40-1993\)](#) and the [Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CXC 23-1979\)](#)]

The products should comply with any microbiological criteria established in accordance with the [Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods \(CXG 21-1997\)](#).

**3.9 PACKAGING**

The packaging provisions in the current Follow-up Formula Standard are identical to those contained within the Infant Formula Standard and have some consistencies with the provisions contained within the Standard for Canned Baby Foods and Standard for Processed Cereal-based Foods for Infants and Young Children.

The eWG was therefore asked if they supported the Chair's proposal to retain the packaging provisions in the current Follow-up Formula Standard for both follow-up formula for older infants and for [name of product] for young children. The Chair does however note that this proposal was in conflict with section 4.2.5.2 of the Consultation Paper, whereby proposed administrative revisions on food additives included moving the permissions for packaging gases (i.e. carbon dioxide and nitrogen) from Section 7 Packaging to Section 4 Food Additives (see section 3.5 of this paper).

The current provisions are as follows;

**7. Packaging**

**7.1** The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.

**7.2** The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

**EWG views**

From the eWG responses, there was majority support (21 CM, 1 CMO, 2 CO) for retaining provisions 7.1 and 7.2 in the current Follow-up Formula Standard (relating to packaging) for both follow-up formula for older infants and for [name of product] for young children.

Three CM and one CO supported leaving a reference to packaging gases in both the Food Additive and in the Packaging sections to avoid any confusion about the permission for the use of these food additives. One CMO noted that 'Packaging gases' is a functional class recognised in the EU and at Codex, and as such nitrogen and carbon dioxide should be listed under that functional class within the Food Additive section as is the approach in the Infant Formula Standard.

One CM suggested an amendment to the text in 7.1 to add clarity, so that it reads;

The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; **[packaging gases shall be used in accordance with Food Additives list in Section X – Food Additives]**. Nitrogen and carbon dioxide may be used as a packing media.

**Conclusion**

As there was majority support for retaining the Packaging provisions within the current Follow-up Formula Standard, it is the recommendation of the Chair that the Committee agree to adopt the text as drafted for follow-up formula for older infants and for [name of product] for young children.

The Chair notes that additionally **Recommendation 8b** recommends that the Committee consider if 'Packaging Gases' should also be included in the Food Additive section and listed under the appropriate functional class.

This approach would assist in avoiding confusion about permission for use of these food additives.

<b>Recommendation 13</b>
<p><b>a) Follow-up formula for older infants:</b></p> <p>That CCNFSDU agree to the following text for 'Packaging' for follow-up formula for older infants;</p> <p><b>Packaging</b></p> <p>The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.</p> <p>The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.</p>
<p><b>b) [Name of product] for young children:</b></p> <p>That CCNFSDU agree to the following text for 'Packaging' for [name of product] for young children;</p> <p><b>Packaging</b></p> <p>The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.</p> <p>The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.</p>

### 3.10 FILL OF CONTAINER

The current provision in the Follow-up Formula Standard for *Fill of containers* is the same as that in the Infant Formula Standard (revised in 2007) and the Standard for Canned Baby Foods. However, the Chair notes the inconsistencies between the standards in the conversion of values in grams to ounces. The provision in the current Follow-up Formula Standard reads as follows;

<p><b>8. Fill of containers</b></p> <p>In the case of products in ready-to-eat form, the fill of container shall be:</p> <p>not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);</p> <p>not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and</p> <p>not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.</p>
--

Conversion and rounding issues were addressed in [CRD 5](#) at CCNFSDU40. A systematic approach was used to convert values from per 100 kcal to 100 kJ using the International System of Units (S.I.) conversion factors and conventional rounding to ensure that a reasonable level of specificity is attained in the converted value.

The conversion factors for grams and ounces are: 1 g = 0.035274 oz.; and 1 oz. = 28.349 g. The rounding rule agreed to for values >5 is to round to the nearest full number. Following these practices results in 150 g to be converted to 5.291 oz. and rounded to 5 oz. and 250 g to be converted 8.818 oz. and rounded to 9 oz.

It was the proposal of the Chair that the text from the current Follow-up Formula Standard for *Fill of containers* be retained for both follow-up formula for older infants and [name of product] for young children, and that the conversion of grams to ounces as well as the rounding follows the approach in CRD 5 at CCNFSDU40 leading to the revised value of 5 oz. (from 5 ½ oz.) as presented below:

#### **Fill of containers**

*In the case of products in ready-to-eat form, the fill of container shall be:*

not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);

not less than 85% v/v for products in the weight range 150-250 g (5 ½- 9 oz.); and

not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

#### EWG views

From the eWG responses there was majority support (20 CM, 1 CMO, 2CO) for the Chair's proposal 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, and for [name of product] or young children, noting the revised level of 5 oz. (from the previous value of 5 ½ oz.).

One CM who supported the recommendation asked that consideration be given to providing the net weight as a means of establishing the amount of fill in the product.

#### Conclusion

As there was majority support for retaining the Fill of containers provisions within the current Follow-up Formula Standard, with a modified level of 5 oz in line with the above conversion and rounding approach, it is the recommendation of the Chair that the Committee agree to adopt the text as drafted for both follow-up formula for older infants and for [name of product] for young children.

<b>Recommendation 14</b>
<p><b>a) Follow-up formula for older infants:</b></p> <p>That CCNFSDU agree to the following text for 'Fill of containers' for follow-up formula for older infants;</p> <p><b>Fill of containers</b></p> <p>In the case of products in ready-to-eat form, the fill of container shall be:</p> <ul style="list-style-type: none"> <li>(i) not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);</li> <li>(ii) not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and</li> <li>(iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.</li> </ul>
<p><b>b) [Name of product] for young children:</b></p> <p>That CCNFSDU agree to the following text for 'Fill of containers' for [name of product] for young children;</p> <p><b>Fill of containers</b></p> <p>In the case of products in ready-to-eat form, the fill of container shall be:</p> <ul style="list-style-type: none"> <li>(iv) not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);</li> <li>(v) not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and</li> <li>(vi) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.</li> </ul>

#### 3.11 METHODS OF ANALYSIS AND SAMPLING

The current provision in the Follow-up Formula Standard for the Methods of Analysis and Sampling is the same as that in the Infant Formula Standard and the Standard for Canned Baby Foods. All three standards refer to the Codex Standard for the Recommended Methods of Analysis and Sampling.

The provision in the current Follow-up Formula Standard reads as follows;

#### **10. Methods of analysis and sampling**

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.

It was the proposal of the Chair that the provision for Methods of Analysis and Sampling in the current Follow-up Formula Standard be retained for follow-up formula for older infants, and for [name of product] for young children.

#### **EWG views**

There was unanimous support from the eWG (21 CM, 1 CMO, 2 CO) for retaining provision 10 in the current Follow-up Formula Standard (relating to methods of analysis and sampling) for follow-up formula for older infants and for [name of product] for young children.

It was noted by one CM that if the [Recommended Methods of Analysis and Sampling \(CXS 234-1999\)](#), where the methods will be listed is expanded in the future to include numeric criteria instead of listing specific methods, this would mean that any method that meets the criteria can be used.

#### **Conclusion**

As there was unanimous support for retaining the Methods of Analysis and Sampling provisions within the current Follow-up Formula Standard, it is the recommendation of the Chair that the Committee agree to adopt the text as drafted for both follow-up formula for older infants and for [name of product] for young children.

If the [Recommended Methods of Analysis and Sampling \(CXS 234-1999\)](#), where the methods will be listed is expanded in the future to include numeric criteria instead of listing specific methods, it is the view of the Chair that this be addressed in the future and most likely through CCMAS and changes to applicable standards as deemed appropriate as part of that work.

#### **Recommendation 15**

##### **a) Follow-up formula for older infants:**

That CCNFSDU agree to the following text for Methods of analysis and sampling for follow-up formula for older infants;

##### **Methods of analysis and sampling**

For checking the compliance with this Standard, the methods of analysis contained in the [Recommended Methods of Analysis and Sampling \(CXS 234-1999\)](#) relevant to the provisions in this standard, shall be used.

##### **b) [Name of product] for young children:**

That CCNFSDU agree to the following text for Methods of analysis and sampling for [name of product] for young children;

##### **Methods of analysis and sampling**

For checking the compliance with this Standard, the methods of analysis contained in the [Recommended Methods of Analysis and Sampling \(CXS 234-1999\)](#) relevant to the provisions in this standard, shall be used.

**APPENDIX II: SECTION 4 FOOD ADDITIVES**

The Table below incorporates the following administrative changes as per discussion in Section 3.5 of this paper:

- Permissions in table format
- The names of the functional classes and individual food additives consistent with the terms used in the GSFA ([CXS 192-1995](#))
- International Number System identifiers (INS) added
- removed the permission for L(+) lactic acid producing cultures
- footnote added that “within the limits for sodium in Section 3.1” is applicable to Follow-up Formula for Older Infants only

Additionally packaging gases (section 4.5) have been included in the table below, noting this is yet to be agreed to (see **Recommendation 8**).

**4. FOOD ADDITIVES**

INS	Additive	Maximum level in 100 mL of the product ready for consumption
<b>4.1 Thickener</b>		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g
<b>4.2 Emulsifier</b>		
322	Lecithin	0.5 g
471	Mono- and Di-glycerides	0.4 g
<b>4.3 Acidity Regulator</b>		
500ii	Sodium hydrogen carbonate	Limited by GMP
500i	Sodium carbonate	
331i	Sodium dihydrogen citrate	
331iii	Trisodium citrate	Within the limits for sodium in Section 3.1*
524	Sodium hydroxide	
501ii	Potassium hydrogen carbonate	Limited by GMP
501i	Potassium carbonate	
332i	Potassium dihydrogen citrate	
332ii	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	L (+) Lactic acid	Limited by GMP
330	Citric acid	Limited by GMP
<b>4.4 Antioxidant</b>		
307b	Mixed tocopherols concentrate	3 mg singly or in combination
307a, c	α-tocopherol	
304	L-ascorbyl palmitate	
300	Ascorbic acid, L-	

301	Sodium ascorbate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304)
302	Calcium ascorbate	
<b>[4.5 Packaging Gases</b>		
290	Carbon dioxide	GMP
941	Nitrogen	GMP ]
4.6 Flavourings <sup>^</sup>		
	Natural Fruit Extracts	GMP
	Vanilla extract	GMP
	Ethyl vanillin <b>[(JECFA no. 893)]</b>	5 mg
	Vanillin <b>[(JECFA no. 889)]</b>	5 mg

\* Applicable to Follow-up Formula for Older Infants only

<sup>^</sup> ***[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]***

**APPENDIX III: LIST OF 2019 EWG PARTICIPANTS****Codex Members & Codex Member Organisation**

- |                        |                 |                                  |
|------------------------|-----------------|----------------------------------|
| 1. Argentina           | 15. India       | 29. The Philippines              |
| 2. Australia           | 16. Indonesia   | 30. Republic of Korea            |
| 3. Brazil              | 17. Iran        | 31. Russian Federation           |
| 4. Canada              | 18. Ireland     | 32. Senegal                      |
| 5. Chile               | 19. Jamaica     | 33. Singapore                    |
| 6. China               | 20. Japan       | 34. South Africa                 |
| 7. Colombia            | 21. Kuwait      | 35. Sweden                       |
| 8. Costa Rica          | 22. Malaysia    | 36. Switzerland                  |
| 9. Dominican Republic  | 23. Mexico      | 37. Thailand                     |
| 10. Ecuador            | 24. Morocco     | 38. United Kingdom               |
| 11. Egypt              | 25. Nepal       | 39. the United States of America |
| 12. The European Union | 26. New Zealand | 40. Vietnam                      |
| 13. France             | 27. Norway      |                                  |
| 14. Guatemala          | 28. Peru        |                                  |

**Codex Observers**

1. Association Européenne pour le droit de l'alimentation (AEDA/EFLA)
2. Calorie Control Council (CCC)
3. Comité Européen des fabricants de sucre (CEFS)
4. Federation of European Specialty Food Ingredients Industries (EUSFI)
5. European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)
6. European Vegetable Protein Association (EUVEPRO)
7. Helen Keller International (HKI)
8. International Association of Consumer Food Organizations (IACFO)
9. International Baby Food Action Network (IBFAN)
10. International Council of Grocery Manufacturers Associations (ICGMA)
11. International Dairy Federation (IDF)
12. International Food Additives Council (IFAC)
13. Institute of Food Technologies (IFT)
14. International Lactation Consultant Association (ILCA)
15. International Special Dietary Foods Industries (ISDI)
16. Specialised Nutrition Europe (SNE)
17. The United Nations Children's Fund (UNICEF)
18. World Sugar Research Organization (WSRO)