

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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World Health
Organization



Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4b

CX/NFSDU 18/40/5

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Fortieth Session
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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

(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 2018/63-NFSDU available on the Codex webpage/Circular Letters 2018:

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

INTRODUCTION

At the 39th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU39), the Committee agreed to continue work on the revision of the Standard for Follow-up Formula ([CXS 156-1987](#)) (hereafter referred to as the Follow-up Formula Standard) and to forward the essential composition requirements for older infants and young children agreed at the 39th and previous sessions to Step 5 for adoption by CAC41 ([REP18/NFSDU](#) Appendix II).

Further to this, the Committee agreed to keep in brackets the Preamble for further discussion at the next session of the CCNFSDU, and to re-establish the electronic working group (eWG) chaired by New Zealand, and co-chaired by France and Indonesia and working in English with the following terms of reference:

Terms of Reference for the electronic working group:

- i. finalise the labelling requirements for follow up formula for older infants (see REP18/NFSDU Appendix III);
- ii. finalise the labelling requirements for [name of product] for young children (see REP18/NFSDU Appendix III);
- iii. consider options for the structure of the standard/standards (e.g. whether one standard or two separate standards for the products for the two age groups);
- iv. develop a proposal for the scope sections for both follow-up formula for older infants and [name of product] for young children consistent with discussions at CCNFSDU39; and
- v. finalise the product definitions contained within section 2.1 for both follow-up formula for older infants and [name of product] for young children and finalise the name of the product for young children.

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Conduct of the Electronic Working Group (eWG) 2018

The eWG (list of participants is presented in Appendix III) has considered three consultation papers during 2018. One consultation paper addressed the Scope, Labelling, Definitions and name of the product for young children (ToRs i., ii., iv. and v.) and was posted on the Codex online platform in May for a five week consultation period. The options for the structure of the standard(s) (ToR iii.) was consulted on separately in two rounds. The first consultation paper on the structure was posted on the online platform in March for a five week consultation period and the second consultation paper on structure in July for a three week consultation period.

Please note the following abbreviations used throughout this paper:

CM: Codex Member CMO: Codex Member Organisation CO: Codex Observer

eWG: Electronic Working Group ToR: Terms of reference

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

Conclusions

The Chairs of the eWG have used feedback from the eWG consultations to prepare this Agenda Paper, which contains 19 recommendations in Appendix I covering the scope, definitions, and labelling for both follow-up formula for older infants and [name of product] for young children, as well as the structure of the standard(s).

Some outstanding issues to be considered in the future review of the Standard are listed below.

1.1 Work for further consideration

Additional sections that are included within the Infant Formula Standard and/or the current Follow-up Formula Standard and which are yet to be discussed and progressed are as presented below. Many of the Sections refer to other Codex Standards or Guidelines that are applicable.

- **Name of the Standard(s)**

Still outstanding is the name of the standard(s) which will be based on what products are covered. According to the Procedural Manual *“The name of the standard should be clear and as concise as possible. It should usually be the common name by which the food covered by the standard is known or, if more than one food is dealt with in the standard, by a generic name covering them all. If a fully informative title should be inordinately long, a subtitle could be added.”*

- **Purity Requirements**

The current Follow-up Formula Standard states that; *‘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’*. This requirement is the same as that contained within the Infant Formula Standard with the exception of the age range.

- **Vitamin Compounds and Mineral Salts**

Both the Infant Formula Standard and the current Follow-up Formula Standard reference the *Advisory Lists of Nutrient Compounds for Use in Foods for Infants and Young Children* ([CXG 10-1979](#)). The Infant Formula and Follow-up Formula Standards state that vitamins and minerals added in accordance with the essential and optional compositional provisions of the respective standards should be selected from this Advisory List.

- **Consistency and Particle Size**

The current Follow-up Formula Standard states that; *‘When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles’*. The Infant Formula Standard includes this requirement and further states that it must be *‘suitable for adequate feeding of young infants’*.

- **Specific Prohibitions**

Both the Infant Formula and Follow-up Formula Standard only have one prohibition listed. That is, *‘the product and its components shall not have been treated by ionizing radiation’*.

- **Food Additives**

The current Follow-Up Formula Standard lists which additives are permitted and states that the carry-over principle (Section 1.4) of the *General Standard for Food Additives* ([CXS 192-1995](#)) shall apply. The Infant Formula Standard includes a more comprehensive list with INS numbers.

- **Contaminants**

The Infant Formula Standard states that; *'The products covered by this Standard shall comply with the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), and that 'the products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission'*. The current Follow-up Formula Standard does not reference CXS 193-1995, and instead includes a requirement for preparation of product under good manufacturing practices.

- **Hygiene**

The current Follow-up Formula Standard references the relevant provisions of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008)*. In addition, the Infant Formula Standard references the *General Principles of Food Hygiene (CXC 1-1969)*, and the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997)*.

- **Packaging**

Both the Infant Formula Standard and the current Follow-up Formula Standard include the same two requirements for packaging which state that: *'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 packing media'*, and that *'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'*.

- **Fill of Container**

Both the Infant Formula Standard and the current Follow-up Formula Standard contain the same requirement for fill of containers.

- **Methods of Analysis and Sampling**

The current Follow-up Formula Standard advises referring to relevant Codex texts on methods of analysis and sampling, whereas the Infant Formula Standard specifically references the *Recommended Methods of Analysis and Sampling (CXS 234-1999)*, and states that relevant provisions shall be used. CCMAS agreed to have CXS 234-1999 as the single reference for methods of analysis in Codex standards and CAC39 adopted amendments to the [Procedural Manual](#) "Format for Codex Commodity Standards" to this effect.

1.2 Additional information on developments since CCNFSDU39

Following CCNFSDU39 there have been two further developments which impact the progression and discussions on the Review of the Follow-up Formula Standard. There has been:

- (a) an addendum issued to the report of CCNFSDU39; and
- (b) the CCEXEC at its 75th session provided commentary and guidance in relation to the Follow-up Formula Review.

(a) The [addendum to the report of CCNFSDU39](#) states:

CORRECTION BY THE WHO OFFICE OF THE LEGAL COUNSEL

With reference to the response provided by the WHO Representative, as reflected in paragraph 13 of the report, concerning the meaning of certain operative verbs in resolutions and decisions adopted by the WHO governing bodies, the following correction is provided:

- *It is WHO Member States that give meaning to the language they use.*
- *Furthermore, in WHO practice, operative terms such as "welcomes," "welcomes with appreciation", "notes," and "notes with appreciation" have different meanings and are not used synonymously with the term "approves." In this regard, the WHO Technical Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was not approved or endorsed but was welcomed with appreciation (see operative paragraph 1 of resolution WHA69.9). Resolution WHA69.9 itself (i.e., the resolution as a whole) was adopted by consensus on 28 May 2016 at the eighth plenary meeting of the Sixty-ninth World Health Assembly.*

(b) In relation to the Review of the Standard for Follow-up formula, the following is recorded in the report of the 75th Session of the Executive Committee of the Codex Alimentarius Committee ([REP18/EXEC2-Rev.1](#) paras 12 - 18):

Review of the Standard for Follow-up formula (CODEX STAN 156-1987)

12. Members discussed the Codex Secretariat's recommendation to address references to WHO/WHA documents within the draft CCNFSDU text on follow-up formula (FUF).

13. The representative of FAO observed that FAO and WHO texts served fundamentally different purposes from Codex standards. The representative of WHO stated that the WHO texts had the objective of protecting consumer health, which was common with Codex.

14. Conclusion

With regard to references to WHO/WHA documents in the draft CCNFSDU text on follow-up formula, CCEXEC75 provided the following advice intended to assist CCNFSDU in moving forward:

- a. references should be considered on a case-by-case basis;
- b. references may provide context and additional information to assist members in understanding and use of standards;
- c. concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex; and
- d. references must be relevant to the scope of the standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

15. CCEXEC75 noted that its advice did not preclude CCNFSDU from formulating specific requests for advice from CCEXEC at its next session, if appropriate.

16. CCEXEC75 also expressed its expectation that CCNFSDU would continue at its next session to complete the other elements, including scope, definitions and labeling, of the Standard for Follow-up formula.

17. CCEXEC75, recalling that similar issues relating to references had arisen in a number of Codex committees, noted that it may give further consideration to the benefit of providing generic advice to committees in this regard.

18. CCEXEC75 further agreed to include the following language on consideration of FAO and WHO policies in the forthcoming Codex Strategic Plan (under paragraph 4.2):

"In conducting its work, the Commission takes into account, where appropriate, the relevant policies, strategies and guidelines of FAO and WHO, consistent with fulfilling its unique mandate to protect the health of consumers and ensure fair practices in the food trade through the development of international food safety and quality standards."

1.3 Timeline

Below is the proposed timeline for completion of this work. Please note that this timeline is dependent on the outcomes of Committee discussions and progress made at CCNFSDU40 and may need to be modified.

December 2018	Consideration of the draft standard and advancement of the scope and labelling sections to Step 5
July 2019	CAC progression of scope and labelling sections to Step 5
December 2019	Completion of the standard and advancement to Step 8 for adoption by CAC
July 2020	CAC adoption of final standard

Recommendation:

The Committee is invited to:

- consider the recommendations of the eWG (see Appendix I); and
- agree the proposed timeline for completion of work (as presented above).

Appendix I

DISCUSSION AND RECOMMENDATIONS OF EWG

During CCNFSDU39 significant progress was made on the labelling provisions for the follow-up formula standard for older infants. Outstanding issues from CCNFSDU39 include the scope and definitions, some text within the introductory paragraph to the labelling section, and section 9.6 Additional Labelling Requirements which remains in square brackets.

Due to time constraints, the Committee did not discuss the proposals for the labelling of product for young children.

With regards to the scope, name of product and product definitions for the standard(s) for follow-up formula for older infants and [name of product] for young children, the following were noted as opinions of some members and observers at CCNFSDU39 (REP18/NFSDU):

- whilst the Committee did not take a decision on the definition for the two products, they noted that some members were of the view that product for both older infants and young children was a breast-milk substitute, others expressed the view that product for young children should not be considered breast-milk substitute as it was not intended to replace breast-milk and was not nutritionally adequate;
- the Committee agreed not to refer to the products as “*specialty*” manufactured; and in the case of the definition for the product for young children to delete the last two sets of text in square brackets;
- the preference for other terms such as “formula for older infants” which would help to better define the product for older infants;
- the term “follow-up” implied that one does follow up, which was not the case and consideration should therefore be given to naming the product “drink for older infants”; and
- the product for young children was meant to be used as part of a diversified diet, but the product for older infants could be part of the overall foods to meet nutritional requirements for this age group.

Whilst the Committee did not discuss the recommendations for the labelling of product for young children at CCNFSDU39 due to time constraints, the Chair of the 2018 eWG proposed that for those generic labelling provisions where agreement was reached for follow-up formula for older infants, these provisions be adopted for [name of product] for young children so as to ensure consistency. These recommendations were presented to the group as part of the eWG consultation.

Referencing of general labelling Guidelines and Standards

It is also noted that there are a number of clauses within the proposed labelling provisions for the standard(s) for follow-up formula for older infants and [name of product] for young children that are the same as other provisions within general labelling Guidelines and Standards. The [Procedural Manual](#) (Section II - *Format for Codex Commodity Standards*, p.53) provides the following:

“Provisions of General Standards, Codes or Guidelines shall only be incorporated into Commodity Standards by reference unless there is a need for doing otherwise.”

Consideration needs to be given to the approach of either referencing the appropriate labelling guideline or repeating the language or part of the language of the provision within the standard(s) for follow-up formula for older infants and [name of product] for young children. Currently this applies to labelling provisions within the *Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)*, the *General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985)*, and the *Guidelines on Nutrition Labelling (CXG 2-1985)*.

1.4 SCOPE

As per ToR iv, the 2018 eWG was charged with developing a proposal for the scope sections for both follow-up formula for older infants and [name of product] for young children. This work was commenced by the 2017 eWG with recommendations put forward at CCNFSDU39, however due to time constraints, the recommendations were not discussed.

At CCNFSDU38 the Secretariat identified that the Scope should be a concise statement in accordance with the Procedural Manual. As presented at CCNFSDU39, and after consultation and discussion in 2017 with WHO and the Codex Secretariat, it was proposed that (if deemed necessary) the Preamble could include any specific references to WHO documents and WHA resolutions, noting that this approach would replace the need to list or reference specific resolutions within different sections in the Standard itself (including the Scope) as the Preamble is applied to the Standard as a whole.

This proposed approach would make provision 1.4 of the Scope (within the current Follow-up Formula Standard) redundant for both follow-up formula for older infants and [name of product] for young children.

Please see the 2017 Agenda Paper for further background on the Scope, including previous eWG comments and discussions ([CX/NFSDU 17/39/4 Rev.1](#)).

The proposals for the Scope put forward to the 2018 eWG for both follow-up formula for older infants and for [name of product] for young children included some minor modifications to that recommended in the 2017 Agenda Paper and are based on the written comments received to that paper.

1.4.1 Scope: Follow-up formula for older infants

1.4.1.1 Section 1.1

From the written comments received¹ to the CX/NFSDU 17/39/4 Rev 1 (hereafter referred to as the 2017 Agenda Paper), there was majority support for the following recommendation as put forward to the Committee at CCNFSDU39 for follow-up formula for older infants:

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

This text was re-presented to the 2018 eWG members for their comment.

eWG views

Thirty three (26 CM, 1 CMO, 6 CO) respondents supported the text as written. A small number of respondents suggested some modifications.

Conclusion

Due to the almost unanimous support for the text as written, it is the recommendation of the Chair that the below text be agreed to by the Committee.

Recommendation 1:

That CCNFSDU agree to the following text for Section 1.1 of the Scope (for follow-up formula for older infants):

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

1.4.1.2 Section 1.2

At CCNFSDU39 the Committee was presented with the following recommended text for their consideration:

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

From the written comments received¹ to the 2017 Agenda Paper, there was majority support for removal of the square brackets around '*labelling and analytical*', although some members did express the view that '*analytical*' was not necessary. The same draft text was presented to the 2018 eWG for their comment.

eWG views

From those who responded to this proposal, 27 (23 CM, 1 CMO, 3 CO) members supported the draft text as presented above. A further three members supported the text, with the exception of the inclusion of '*analytical*'. Two members modified the text to include '*use*'; '*This section of the Standard contains compositional, quality, safety, use, labelling and analytical requirements for Follow-up Formula for Older Infants.*'

Conclusion

Due to the majority preference for supporting the text as proposed, it is the recommendation of the Chair that the below text be agreed to by the Committee.

Recommendation 2:

That CCNFSDU agree to the following text for Section 1.2 of the Scope (for follow-up formula for older infants):

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

¹ CX/NFSDU 17/39/4 Add.1 and Add.2

1.4.1.3 Section 1.3

At CCNFSDU39, the Committee was presented with the following recommendation for Section 1.3 of the Scope for Follow-up Formula for Older Infants and were asked to select their preferred terminology (should vs shall):

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

Whilst the Committee did not discuss this recommendation, from the written comments received¹ to the 2017 Agenda Paper, there was majority support for 'shall' and deletion of 'should' within Section 1.3. The use of 'shall' would be more consistent with the terminology used in the labelling section of the Standard and therefore this preference was put forward to the 2018 eWG for their comment.

eWG views

Thirty eWG respondents (23 CM, 1 CMO, 6 CO) supported the proposal to use 'shall' within Section 1.3. Three CM were in favour of 'should' and a further three members (1 CM, 2 CO) proposed alternative wording for 'should/shall be presented as...'; including; 'shall be named as...' and 'shall be marketed as...'.

Conclusion

In line with the majority of the 2018 eWG, it is the recommendation of the Chair that the below text be agreed to by the Committee.

Recommendation 3:

That CCNFSDU agree to the following text for Section 1.3 of the Scope (for follow-up formula for older infants):

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

1.4.2 Scope: [Name of product] for young children

1.4.2.1 Section 1.1

From the written comments received¹ to the 2017 Agenda Paper, there was majority support for the following recommendation as put forward to the Committee at CCNFSDU39 for [name of product] for young children:

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

This text was re-presented to the 2018 eWG members for their comment.

eWG views

Thirty two eWG respondents (26 CM, 1 CMO, 5 CO) supported the text as proposed. Three respondents (1 CM, 2 CO) suggested the following text be added to Section 1.1: '*...intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants*', and one CO proposed that the statement be modified to clarify that the liquid form could be '*ready to use or concentrated*'.

Conclusion

In line with the majority of the 2018 eWG, it is the recommendation of the Chair that the below text be agreed to by the Committee, noting that discussion on whether [name of product] for young children should be defined as a breast-milk substitute (or not) falls within the Definition of the product, not within the Scope.

Recommendation 4:

That CCNFSDU agree to the following text for Section 1.1 of the Scope (for [name of product] for young children):

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

1.4.2.2 Section 1.2

At CCNFSDU39, the Committee was presented with the following text for Section 1.2 for their consideration:

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

From the written comments received¹ to the 2017 Agenda Paper, there was majority support for removal of the square brackets around '*labelling and analytical*'. Some members did express the view that '*analytical*' was not necessary.

eWG views

From the responses received, 28 eWG members (24 CM, 1 CMO, 3 CO) supported the proposed draft text (with the inclusion of '*labelling and analytical*'). A further five members supported the text with the exception of the inclusion of '*analytical*'. Two members modified the text to include 'use'; '*This section of the Standard contains compositional, quality, safety, use, labelling and analytical requirements for [name of product] for young children.*'

Conclusion

Due to the majority preference for supporting the text as proposed, it is the recommendation of the Chair that the below text be agreed to by the Committee.

Recommendation 5:

That CCNFSDU agree to the following text for Section 1.2 of the Scope (for [name of product] for young children):

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

1.4.2.3 Section 1.3

At CCNFSDU39, the Committee was presented with the following recommendation for Section 1.3 of the Scope for [name of product] for young children and were asked to select their preferred terminology (should vs shall).

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

Whilst the Committee did not discuss this recommendation, from the written comments received¹ to the 2017 Agenda Paper, there was majority support for '*shall*' and deletion of '*should*' within Section 1.3. The use of '*shall*' would be more consistent with the terminology used in the labelling section of the Standard and therefore this preference was put forward to the 2018 eWG for their comment.

eWG views

Thirty one eWG respondents (24 CM, 1 CMO, 6 CO) supported the use of '*shall*'. Two CM indicated their preference for '*should*' and three respondents (1 CM, 2 CO) suggested the text be modified to read '*should/shall be marketed as...*' rather than '*shall be presented as ...*'.

Conclusion

In line with the majority of the 2018 eWG, it is the recommendation of the Chair that the below text be agreed to by the Committee.

Recommendation 6:

That CCNFSDU agree to the following text for Section 1.3 of the Scope (for [name of product] for young children):

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

1.5 PRODUCT DEFINITIONS

As per ToR v. the 2018 eWG has been asked to finalise the product definitions contained within Section 2.1 for both follow-up formula for older infants and [name of product] for young children.

Whilst the Committee did not take a decision on the definition for these two products at CCNFSDU39, it was agreed not to refer to the products as '*specialty*' manufactured; and to delete the last two sets of texts in square brackets in the definition of product for young children (as presented in section 1.5.2 below).

Furthermore, the following opinions of some members and observers (relevant to the definitions) were noted (REP18/NFSDU, para 64):

- the name of the product should clearly state that the product for both older infants and young children was a breast-milk substitute;

- the product for young children should not be considered breast-milk substitutes as it was not intended to replace breast-milk and was not nutritionally adequate;
- the preference for other terms such as “formula for older infants” which would help to better define the product for older infants; and
- the product for young children was meant to be used as part of a diversified diet, but the product for older infants could be part of the overall foods to meet nutritional requirements for this age group.

As per Appendix III, Part I of the Report of the 37th Session of CCNFSDU ([REP16/NFSDU](#)), the Committee has already agreed to the below definitions contained within section 2.2 – Other Definitions, of the Follow-up Formula Standard.

2.2	Other Definitions
2.2.1	The term infant means a person of not more than 12 months of age.
2.2.2	The term older infant means a person from the age of 6 months and not more than 12 months of age.
2.2.3	The term young child means a person from the age of more than 12 months up to the age of three years (36 months).

1.5.1 Follow-up formula for older infants

During 2017, the eWG considered whether the definition of follow-up formula for older infants should reference what it is replacing in the diet (i.e. breast-milk and/or infant formula). As a result of 2017 eWG discussions and comments, the definition evolved with various proposals presented to the group. After the second round of consultation and based on comments received from the eWG, the Chair proposed a definition that did not include a reference to what follow-up formula for older infants is replacing in the diet (i.e. breast-milk and/or infant formula), and the following recommendation for the definition of follow-up formula for older infants was put forward for Committee consideration at CCNFSDU39:

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

The draft definition for follow-up formula for older infants further evolved during CCNFSDU39. Whilst the Committee did not specifically consider the recommendation within the Agenda Paper ([CX/NFSDU 17/39/4 Rev.1](#)), various opinions and views were noted in the report and the following revised definition was presented in [REP18/NFSDU Appendix III](#):

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

The 2018 eWG were consequently asked to consider the modified definition for follow-up formula for older infants included in the report of CCNFSDU39 (and as presented above).

eWG views

The current proposal is for two product definitions; one for follow-up formula for older infants, and one for [name of product] for young children. One CMO has consistently supported a broad and simple definition, similar to the approach taken in the current Follow-up Formula Standard, which covers both products for older infants and for young children. This respondent has also commented that should the majority view of eWG members be in support of two different definitions, they can accept this approach but want the following comment noted; they are *‘not convinced by the inclusion of the text “as a substitute for breast-milk” taking into account the different views on what a breast-milk substitute is’*.

Whilst 27 eWG respondents (25 CM, 2 CO) supported the deletion of ‘specially’ within the product definition for follow-up formula for older infants, seven respondents (5 CM, 2 CO) preferred it be retained.

With respect to the inclusion of the text *‘for use as a substitute for breast-milk’*, 26 eWG respondents (21 CM, 5 CO) supported this text, and seven members (4 CM, 1 CMO, 2 CO) opposed. Other comments that were received included;

- replace *‘substitute for breast-milk’* with *‘breast-milk substitute’*
- delete *‘progressively diversified’*
- modify to say *‘when complementary **foods are** introduced’*
- modify to say *‘progressively diversified **and balanced** diet’*

- modify to say ‘*manufactured to be **nutritionally adequate** for use as*’
- add the statement: ‘*Follow-up formula are not necessary for the growth and development of older infants*’ to the end of the definition.

Conclusion

The preference of the majority of eWG respondents is for the deletion of ‘*specially*’ and for defining follow-up formula for older infants as a substitute for breast-milk. The view of the CMO to not include a reference to breast-milk is noted. The suggested edits to the text as noted in comments above are not supported by a large number of respondents and therefore have not been included in the recommended proposal put forward by the Chair.

Based on the comments received from the 2018 eWG respondents, it is the recommendation of the Chair that the below definition for follow-up formula for older infants be agreed to by the Committee.

Recommendation 7:

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

{**Follow-up formula for older infants** means a product, **specialy** manufactured for use **as a substitute for breast-milk**, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.}

1.5.2 [Name of product] for young children

During 2017 the definition for [name of product] for young children was consulted on twice. As a result of comments received to the first round of consultation, three new proposals for defining product for young children were put to the 2017 eWG for their consideration. Views expressed during the second consultation round included majority support for a definition which does not define the product as a breast-milk substitute. There was also unanimous support for the inclusion of ‘*a liquid part*’ and majority support for ‘*diversified diet*’ within the definition. Based on the comments received from the 2017 eWG, the definition evolved with the below resultant definition being put forward in 2017 for Committee consideration:

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

Noting the agreement of the Committee at CCNFSDU39 to not refer to products as ‘*specialy*’ manufactured and in the case of product for young children to delete the last two sets of text in square brackets, the definition further evolved to that presented in [REP18/NFSDU Appendix III](#) and replicated below:

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

Consequently, the 2018 eWG members were asked to consider and comment on the modified definition for [name of product] for young children as drafted and presented in the report of CCNFSDU39.

eWG views

The current proposal is for two product definitions; one for follow-up formula for older infants, and for [name of product] for young children. One CMO has consistently supported a broad and simple definition, similar to the approach taken in the current Follow-up Formula Standard, which covers both products for older infants and for young children. This respondent has also commented that should the majority view of eWG members be in support of two different definitions, they can accept this approach but want the following comment noted; they do not ‘*consider it necessary to introduce in the definition references to breast-milk substitutes taking into account that different views exist on what a breast-milk substitute is*’. Furthermore, they are of the view that it is ‘*difficult to anticipate how follow-up formula is consumed*’, as a replacement for breast-milk or as well as breast-milk, in the diets of older infants and young children. They consider that the issue is more complicated for product for young children ‘*taking into account that after one year of life, cow’s milk consumption is also recommended in the diet and the product can also replace/integrate cow’s milk consumption*’.

The 2018 eWG members were polarised in their views on the definition for [name of product] for young children and the inclusion of the text ‘*as a breast-milk substitute*’. From those members who responded to the proposal 15 (10 CM, 5 CO) supported the inclusion of ‘*as a breast-milk substitute*’ and 16 (13 CM, 1 CMO, 2 CO) opposed its inclusion.

The eWG was also divided in its comments on the proposed deletion of the following text; ~~**[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements]**~~ with some members commenting that the definition should capture the role and purpose of this product.

- Support for deleting the text contained within both sets of square brackets: (12 CM, 3 CO). An additional 2 CO's requested the definition also include the statement '*[name of product] for young children are not necessary for the growth and development of young children.*'
- Support for retaining the text contained within both sets of square brackets; (1 CM)
- Support for retaining **[in order to contribute to the nutritional needs of young children]** only: (6 CM, 1 CO). An additional CM requested the definition be modified to also include the statement '*It should not share branding with infant formula, nor be promoted, since this would undermine breastfeeding and the consumption of culturally appropriate and more nutritious bio-diverse family foods.*'
- Support for retaining **[when nutrient intakes may not be adequate to meet nutritional requirements]** only: (3 CM, 1 CO)

As presented above, there was a slight preference for deletion of the text contained within both sets of square brackets; 17 members (12 CM, 5 CO), compared to a total of 13 members (11 CM, 2 CO) favouring retention of one or more of the text options presented. Of those 13 members, eight favoured retaining the statement **[in order to contribute to the nutritional needs of young children]**. Comment was received that the role and purpose of this product will be lost if the text contained within one or both sets of square brackets is deleted. Four CM's refrained from making any comment on the proposal and one CMO presented a modified definition covering both follow-up formula products.

Some respondents also provided comment on the proposal; ~~especially **[formulated and]** and **[progressively]** **[diversified]**~~. One CM who considers *[Name of product]* for young children to be supplementary in nature, supported the deletion of '*progressively*' and '*diversified*' as these do not align with this concept. An additional CM also supported deletion of both terms, although a reason for this preference was not provided. The majority of respondents to this proposal supported the text as drafted (16 CM, 2 CO), whereas eight respondents favoured retaining both terms; '*progressively diversified*' (4 CM, 1 CMO, 3 CO). There was also a small number of respondents who were in favour of retaining '*specially*'. Justification for this position noted the discussions at CCNFSDU39 on the particular nutritional requirements of young children that this product is aiming to address, and hence the appropriateness of retaining this descriptor for this product category.

Conclusion

Given the near equal split in views on the inclusion of the text '*as a breast-milk substitute*' in the definition for *[name of product]* for young children, and noting the majority support from the 2017 eWG for a definition which does not define the product as a breast-milk substitute, the Chair recommends in this instance that the recommendation put forward for Committee agreement is weighted to the preference of the CMO (representing 28 Member Countries) to **not** classify these products '*as a breast-milk substitute*'.

The Chair also notes the split in views on whether the text contained within the square brackets should be deleted or retained (17 respondents vs 13 respondents respectively); ~~**[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements]**~~.

To assist the discussions, on how *[name of product]* for young children is defined, the Chair has replicated below the principles that guided the proposed mandatory (core) composition of this product.

Principles for the mandatory (core) composition of product for young children
<p>Evidence to support:</p> <ol style="list-style-type: none"> 1. contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate; and/or 2. contribution of adequate amounts of key nutrients from cows' milk, where such nutrients are key contributors to the diet of young children; and/or 3. the nutritional quality and integrity of product to ensure nutritional safety.

The Chair therefore proposes that **[in order to contribute to the nutritional needs of young children]** (as the preferred option), and as captured within Principle 1 above, be retained in square brackets for further discussion at CCNFSDU40. It is the recommendation of the Chair that the remainder of the proposed draft definition be agreed to as presented below.

Recommendation 8:

That CCNFSDU agree to the following definition for [name of product] for young children, and make a decision on whether to retain or delete the text contained within [] :

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

1.6 LABELLING**1.6.1 Follow-up formula for older infants****1.6.1.1 Introductory paragraph**

At CCNFSDU39, the Committee noted the diverse views on whether to include in the introductory paragraph text explaining that the requirements included a prohibition on the use of nutrition and health claims, from the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) in addition to referencing the applicability of the Guidelines.

Those in favour of including the text noted that the proposed wording was consistent with the Infant Formula Standard, and that it was necessary to reiterate and clarify that nutrition and health claims were not appropriate for older infants. It could however be viewed that the inclusion of the text in square brackets is a replication of what is already covered by the *Guidelines for Use of Nutrition and Health Claims*, and as such, there is no need to repeat this statement.

The 2018 eWG were asked to comment on the below draft text for the Introductory Paragraph and state their preference for the text in square brackets being retained or deleted.

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

eWG views

Those 2018 eWG members (11 CM, 3 CO) in favour of retaining the statement '*These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation*', were of the view that as this statement is contained within the Infant Formula Standard, it should be included in the Follow-up Formula Standard for consistency and clarification. Retaining the statement was also seen by some as an important mechanism for highlighting and emphasising the prohibition on the use of nutrition and health claims on foods for infants and young children.

Those members (1 CMO, 14 CM, 5 CO) supporting deletion of the statement were of the view that as this prohibition is already contained within the *Guidelines for Use of Nutrition and Health Claims* there is no need to reiterate it within this Standard. Some noted that as the text and prohibition is covered elsewhere, it is redundant and should therefore be deleted.

Conclusion

It is the preference of 20 eWG respondents (including one CMO) to delete the statement, compared to 14 respondents in support of retaining the statement. The CMO did comment that whilst it was their preference to delete the text as it is already covered by the Guidelines, 'for the sake of consistency with the Infant Formula Standard' they can also agree to retain the text in question if there is strong support within the eWG to do so.

It is the recommendation of the Chair that the below proposal be agreed to by the Committee, noting that the prohibition on nutrition and health claims on foods for infants and young children is contained within the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) and the slight majority supporting this approach.

Recommendation 9:

That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for follow-up formula for older infants:

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

1.6.1.2 Additional labelling requirements

The Infant Formula Standard contains additional labelling requirements which are largely based on Article 4 of the WHO **International Code of Marketing of Breast-milk Substitutes**. By comparison, the current Follow-up Formula Standard only has one additional requirement which is that the *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'*.

In the 2017 1st Consultation Paper, the eWG was asked to consider whether this requirement under section 9.6 of the current Follow-up Formula Standard should be retained for follow-up formula for older infants. There was majority support for not retaining this statement.

There was general agreement amongst 2017 eWG members that the labelling of follow-up formula for older infants should not discourage breastfeeding, nor should Section 9.6 be more stringent than that required on the label of infant formula. In response to questions on Section 9.5 – Information for Use, several members commented on the need to communicate on the label of follow-up formula for older infants the importance of continued breastfeeding. It was proposed that statements relating to breastfeeding should sit under Section 9.6 as per the approach taken in the Infant Formula Standard.

The current provisions in the Infant Formula Standard are as follows:

9.6 Additional Labelling Requirements

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

- a) the words "important notice" or their equivalent;
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

Further comments were received at CCNFSDU39 in relation to Section 9.6 – Additional Labelling Requirements for follow-up formula for older infants. The following points were considered and views expressed;

- a proposal to insert in 9.6.1 c) an exception to introduce the product to infants under 6 months as there might be situations where the product could be introduced earlier under medical supervision. Delegations questioned this proposal noting that it would imply that the follow-up formula was meant to deal with special dietary needs for which it was not intended for. The representative of WHO expressed concern over the ambiguity of the proposed wording, as it failed to qualify why and when exceptions are justified, thereby creating opportunities for inappropriate promotion of the product for use below 6 months of age. For infants below 6 months of age, who do not receive breast-milk for legitimate reasons, infant formula should be available up to, and where needed beyond, 6 months. Therefore WHO did not agree with the proposed wording (REP18/NFSDU para 61);

- a question was raised on why it was needed to refer to independent health workers, as all health workers were professionals and independent;
- the need to reference the International Code of Marketing of Breast-milk Substitutes and subsequent WHA resolutions, especially WHA69.9, in this section; and
- the need to finalise the Preamble first, before the labelling provisions can be finalised.

The Chair notes the comments above. Following CCNFSDU39 two developments have since occurred that are of interest as they relate to some of the views expressed. They are an addendum to the Report of CCNFSDU39 that has since been issued, and the commentary and guidance provided by CCEXEC at its 75th session in relation to the Follow-up Formula Review (See [1.2](#) of this paper for detail).

With regards to Section 9.6 Additional Labelling Requirements for follow-up formula for older infants, the following text was presented to the 2018 eWG for their consideration and comment. The proposed text for Section 9.6 is as presented in REP18/NFSDU Appendix III and what was put forward in the 2017 Agenda paper (CX/NFSDU 17/39/4 Rev.1) for discussion at CCNFSDU39. The Agenda paper further noted that some modifications to the provisions may be required to ensure that Section 9.6 is not more stringent than that required on the label of infant formula.

[9.6 Additional Labelling Requirements

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

{a) the words "important notice" or their equivalent;}

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

{c) a statement that the product should only be used on advice of an [independent] health worker as to the need for its use **[including any exception to the age of introduction of 6 months]** and the proper method of use.}

{d) the statement; 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'.}

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

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

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

9.6.2.3 recommend or promote bottle feeding;

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

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

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

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

eWG views

9.6.1

From the comments received from eWG members there was a preference for the deletion of 'independent' within 9.6.1(c) (15 responses) compared with those in support of retaining (9 responses). Some members supporting deletion provided justification for their position. Justifications included; 'all health workers are professionals and independent' therefore no need to include, and the term 'independent' is not clear and should not be included unless accompanied by a definition.

In regards to the text **[including any exception to the age of introduction of 6 months]** within 9.6.1 (c), 18 respondents (16 CM, 2 CO) supported deletion of this statement. One CMO stated that although their preference was to retain a modified version of this statement so that it was clear when exceptions are justified, **[including any exception to the age of introduction of 6 months based on the individual infants specific growth and development needs]**, they could accept deletion of the proposed text within the square brackets if there was significant support from within the eWG for its omission. There was minimal support from those who responded for retaining the text (1 CM, 1 CO, 1 CMO – noting they can support deletion if this is the majority preference).

There were some suggestions for a modified text within 9.6.1 (c), however these modifications were not supported by a significant number of respondents.

With regards to provision (d), 15 respondents (13 CM, 2 CO) supported retaining this statement, compared to nine (6 CM, 3 CO) who favoured deletion. Several members cited WHA69.9 as justification for retaining (d). Reasons for deletion included the comment that it is more stringent than that required for infant formula, this information would be provided by a health worker as recommended within (c), and this information is already covered at the beginning of 9.6.1 (provisions (a) and (b)). Three CO's commented that if the product is considered a breast-milk substitute, it replaces breast-milk by definition and therefore provision (d) is confusing. Two members in support of retaining the statement suggested a modified version that replaces 'must' with 'shall'.

There was some support for one paragraph for 9.6.1 (4 CM) combining all provisions. The following text was proposed:

'The label of follow-up formula for older infants should not discourage breastfeeding. It must include the following statement: Breastmilk is best for your baby. Infants should be breastfed exclusively for the first 6 months of life and breastfed until they are two years of age or older.' The underlined text was supported by seven respondents in their comments.

9.6.2

From those respondents who commented on the introductory statement for 9.6.2, 12 CM supported the proposed text. There were some proposals for modification, with most of these requesting that 'older infants' be added.

9.6.2.1, 9.6.2.2, 9.6.2.3

Whilst no recommendations were made to alter the text presented in these provisions, a couple of minor editorials were proposed, and in addition seven respondents (6 CM, 1 CO) recommended that the text '(including references to milestones and stages)' within 9.6.2.2 be deleted. An additional CM asked for clarification as to the meaning of this text.

9.6.2.4

It would appear that some duplication with other requirements appears within this provision as noted in some eWG responses. With regards to the statement; ~~that makes a comparison to breast-milk~~ of those members who commented on this provision, 15 respondents (13 CM, 2 CO) supported deletion, whereas eight respondents (5 CM, 1 CMO, 2 CO) favoured retention of this text. Many respondents also commented on the proposed text '~~...suggests that the product is nearly equivalent to or superior to breast-milk~~'. Of those who provided comment on this provision, 11 respondents (9 CM, 1 CMO, 1 CO) supported the text as proposed, whereas 11 respondents (8 CM, 3 CO) supported retention of 'nearly'. Six eWG respondents (5 CM, 1 CO) proposed further modifications to the text to the effect of; 'to suggest that the product is nearly equivalent, [equivalent to] or superior to breast-milk'.

9.6.2.5

From those eWG members who commented on this provision, there was majority support for retaining it (19 CM, 5 CO) with approximately half of those in support, proposing the text be modified. Two CM's requested the provision be deleted and the comment was made that the provision is inconsistent and more stringent than that required by the Infant Formula Standard, and furthermore, there is a lack of clarity around what might be considered an 'endorsement'.

Suggestions for modified text included strengthening the provision to clarify that no form of endorsement is permitted, including by individuals, groups or organisation. Several members commented that they could not support the text *[anything that may be construed as an endorsement]* and others requested that *[unless this has been specifically approved by relevant national, regional or international regulatory authorities]* be deleted as this allows for endorsement.

9.6.3

There was majority support for this provision as drafted, including deletion of the text in square brackets.

9.6.4

The proposed drafting for provision 9.6.4 polarised the eWG. Six respondents (5 CM, 1 CO) supported deletion of the text in square brackets, with several members expressing concern that the wording as proposed could be misinterpreted and taken to encourage the use of sequential numbers/stages and colours and images to make a clear distinction between products, which is in conflict with the outcome that this provision is aiming to achieve. These members were of the view that the text, without the addition of that presented in square brackets is sufficient to avoid misinterpretation or confusion among consumers.

A further 11 respondents (7 CM, 4 CO), supported the first half of the proposed text, but not the second statement. The text would therefore read; **to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.**

Contrary to this view, 12 respondents (9 CM, 1 CMO, 2 CO) supported the proposed text contained within the square brackets, with some citing alignment with recommendation 5 of WHA69.9 as justification for this position.

Conclusion

Many of the comments received on Section 9.6 and the proposals for new or modified text would result in some duplication within this Section. The Chair supports the view that the Standard should be clear and concise and that duplication is not necessary. Furthermore, the approach taken by previous eWG's has been that *'any additional labelling requirements for follow-up formula for older infants should not be more stringent than what is required on the label of infant formula'* (CX/NFSDS 17/39/4 Rev. 1).

With respect to provision 9.6.1, the Chair recommends that the text in square brackets contained within provision (c) be deleted and provision (d) also be deleted and therefore presented with strikethrough. As raised by several eWG members, provision (d) is in direct conflict with the proposed definition for follow-up formula for older infants where there is majority support for a definition that defines follow-up formula as a substitute for breast-milk (see section 1.5.1 of this paper).

Regarding provision 9.6.2 the Chair recommends that the Committee further discusses the current drafting of the provisions within 9.6.2. The Chair suggests that the Committee may wish to reconsider these provisions in light of the addendum to the report of CCNFSDU39 that was published after the consultation paper addressing these labelling provisions was released to the 2018 eWG for comment, and in their deliberations ensure that any new or modified labelling provisions are not more stringent than those required on the label of infant formula as this is the approach that has been taken by previous eWG's.

Due to the almost unanimous support for provision 9.6.3 as drafted, the Chair recommends it be adopted and the text in square brackets with strikethrough be deleted.

Noting the concern expressed by some members of the eWG as to the wording of provision 9.6.4 and whether this could be misinterpreted, the Chair proposes the Committee consider the revised draft text as suggested by 11 respondents.

Recommendation 10:

That CCNFSDU agree to the following text for Section 9.6 for follow-up formula for older infants and that the Committee consider the text presented within the individual provisions within square brackets, or with strikethrough.

{9.6 Additional Labelling Requirements

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

- a) the words "important notice" or their equivalent;
- b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;
- c) a statement that the product should only be used on advice of an ~~[independent]~~ health worker as to the need for its use ~~[including any exception to the age of introduction of 6 months]~~ and the proper method of use.
- ~~[d) the statement; 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding']~~

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

<p>9.6.2.1 idealize the used of follow-up formula for older infants;</p> <p>9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);</p> <p>9.6.2.3 recommend or promote bottle feeding;</p> <p>9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;</p> <p>9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]</p> <p>9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. [In addition, the product should not be compared to breast-milk].</p> <p>9.6.4 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.]]</p>
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1.6.2 [Name of product] for young children

1.6.2.1 Introductory paragraph

Noting the discussions and views expressed at CCNFSDU39, on the introductory paragraph for the labelling section for follow-up formula for older infants (see section 1.6.1.1 of this paper), the 2018 eWG were asked to consider whether the same approach could follow for [name of product] for young children.

As presented in the Agenda Paper for CCNFSDU39 (CX/NFSDU 17/39/4 Rev.1), there was almost unanimous support from the 2017 eWG for the inclusion of an introductory paragraph to the labelling section for [name of product] for young children which includes a reference to applicability of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) and the *Guidelines on Nutrition Labelling* (CXG 2-1985). Furthermore, there was also majority support for the recommendation that a reference to the applicability of the recommendations in the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) to [name of product] for young children be included within the introductory paragraph of the labelling section.

The 2017 Agenda Paper communicated that it would appear that the current wording of section 1.4 of the Scope for the *Guidelines for Use of Nutrition and Health Claims* which states that; '*Nutrition and health claims shall not be permitted for foods for infants and young children **except where specifically provided for in relevant Codex standards or national legislation***' (emphasis added) would allow for national authorities to include provisions for claims (that align with national nutritional policies) on [name of product] for young children in their own national legislation.

It was therefore recommended in the Agenda Paper that the following proposed wording for the introductory paragraph be adopted and a position be maintained whereby nutrition and health claims are not permitted on [name of product] for young children unless specifically provided for in relevant Codex Standards or national legislation:

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

The 2018 eWG were asked to consider this recommendation, taking account of the discussions had for follow-up formula for older infants on whether to include in the introductory paragraph text, from the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) explaining that the requirements include a prohibition on the use of nutrition and health claims.

eWG views

Within the 2018 eWG, there were 13 respondents (11 CM, 2 CO) supporting retaining the statement: '*These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.*' Support for this approach was largely based on the view that it was important to reiterate and highlight this prohibition which is specifically relevant and related to foods for infants and young children, and furthermore it is consistent with the approach taken in the Infant Formula Standard.

Contrary to this view, 19 respondents (14 CM, 1 CMO, 4 CO) supported deletion of the text in question as it is a duplication of what is already covered within the *Guidelines for Use of Nutrition and Health Claims* and is therefore redundant and need not be repeated in this Standard.

Two respondents (1 CM, 1 CO) suggested a modified statement allowing for nutrition and health claims provided 'they have been demonstrated in rigorous studies with adequate scientific standards'.

Conclusion

It is the preference of 19 eWG respondents (including one CMO) to delete the statement, compared to 13 respondents in support of retaining it. The CMO did comment that whilst it was their preference to delete the text as it is already covered by the Guidelines, 'for the sake of consistency with the Infant Formula Standard' they can also agree to retain the text in question if there is strong support within the eWG to do so.

It is the recommendation of the Chair that the below proposal be agreed to by the Committee, noting that the prohibition on nutrition and health claims on foods for infants and young children is contained within the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) and submitter preference for supporting this approach.

Recommendation 11:

That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for [Name of product] for young children:

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

1.6.2.2 Name of Product

At CCNFSDU39, the Committee agreed to Sections 9.1.1, 9.1.2 and 9.1.3 relating to the name of the product for follow-up formula for older infants. With respect to 9.1.4, the Committee agreed to split this provision into two parts in order to clearly explain that the name of the food may also contain a reference to the source of protein. The proposal was further amended to indicate that in the case of mixed protein source products, the source of both the animal and plant proteins should be indicated in the name of the product, with the main source being mentioned first. In addition, the Committee agreed to use the term 'shall' in Section 9.1.5 instead of 'may'.

The 2018 consultation paper proposed that Section 9.1 – Name of Product for [name of product] for young children adopt the approach agreed to at CCNFSDU39 for follow-up formula for older infants as described above to ensure consistency and presented the following for the eWG to consider:

9.1 The Name of the Product

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

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

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

a) If [name of animal] milk is the only source of protein{*}, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk {protein}'.

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

c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein' or 'Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein'.

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

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

The Chair acknowledges an editorial in 9.1.3 c) where 'Follow-up Formula for Older Infants' should have been replaced with '[Name of product] for Young Children'.

eWG views

There was majority agreement (1 CMO, 24 CM, 7 CO) among the respondents to adopt the provisions under Section 9.1 that were already agreed to for follow-up formula for older infants for [name of product] for young children. There were a couple of suggestions made to modify some of the provisions. Two respondents (1 CM, 1 CO) did not consider 'regional' necessary within 9.1.2. Four respondents (3 CM, 1 CO) suggested the deletion of the word 'protein' after 'milk' in 9.1.3 a) and c) stating that '[Name of animal] milk' would be sufficient. One respondent supported a simpler approach for 9.1.3 with only the first line 'The sources of protein in the product shall be clearly shown on the label' retained as that would allow for appropriate identification and noted that *General Standards for the Labelling of Prepackaged Food* (CXS 1-1985) specifies that foods and ingredients known to cause hypersensitivity should be declared. Another respondent considered that 9.1.3 is not clear in that the first line uses 'shall' but in a) through to d) 'may' is used. They suggested to clarify the first line in 9.1.3 by modifying it to 'The sources of protein in the product shall be clearly shown on the label **[and may appear in the name of the product]**', if the intent of the provision is that the protein source need not be declared within the name of the product. The eWG respondents supported the use of 'shall' in 9.1.4 almost unanimously with only one respondent in favour of 'may'.

Conclusion

Noting the majority support of the 2018 eWG for the proposal, it is the recommendation of the Chair that Section 9.1 – Name of Product for [name of product] for young children adopt the approach agreed to for follow-up formula for older infants.

Recommendation 12:

That CCNFSDU agree to the following text for The Name of Product Section 9.1 for [Name of product] for Young Children:

9.1 The Name of the Product

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

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

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

a) If [name of animal] milk is the only source of protein[*], the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk {protein}'.

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

c) **if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein' or '[Name of Product] for Young Children Based on [name of plant] protein and [name of animal] milk protein'.**

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

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

1.6.2.3 List of Ingredients

At CCNFSDU39, the Committee agreed to Section 9.2 – List of Ingredients, for follow-up formula for older infants which included an amendment to delete the reference to 'optional ingredients'.

As part of the 2018 eWG consultation on the Scope, Labelling and Definitions, it was proposed that Section 9.2 – List of Ingredients for [name of product] for young children adopt the approach agreed to at CCNFSDU39 for follow-up formula for older infants to ensure consistency. Electronic working group members were therefore asked to comment on the following text:

9.2 List of Ingredients

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

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate functional classes for these ingredients and additives may be included on the label.** ~~[The food additives INS number may also be optionally declared the INS number].~~

eWG views

From those eWG respondents who commented on this draft provision, there was majority support (21 CM, 1 CMO, 3 CO) for the text as drafted, particularly for 9.2.1. Whilst some respondents commented that they could support provision 9.2.2, several members raised some issues with the drafting of this provision, specifically as it relates to the List of Ingredient provisions within the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). Comment was made that the labelling of ingredients is captured within the General Standard and therefore need not be repeated within the Follow-up Formula Standard. Furthermore, the indication of the functional class of additive (as presented in the above proposed drafting) is optional, whereas it is mandatory within the General Standard, this approach would thus see an exception to the General Standard. It was also communicated by one CO that it is clear that food additives may be preceded by their functional class in order to explain their role, the respondent was however unclear about the functional classes for the other 'ingredients of animal or plant origin' which are not defined.

Conclusion

The Chair proposes that provision 9.2.1 be agreed to as drafted. Noting the comments presented by several eWG respondents in relation to provision 9.2.2, the Chair proposes that this provision be modified slightly. The Chair recommends that the indication of the class name of additives remain optional as this is also the case for infant formula and thus consistent with the approach that the labelling provisions for [name of product] for young children should not be more restrictive than those for infant formula. The Chair also recommends to realign the language regarding the class names with that in the Infant Formula Standard, and thus the deletion of 'functional'. The Chair notes that this would follow the terminology used in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) where 'functional' is specific to additives only. The Chair acknowledges that in order to maintain consistency, this may result in the need to also realign provision 9.2.2 for follow-up formula for older infants, which was discussed and agreed to at CCFSDU39.

Recommendation 13:

That CCFSDU agree to the following text for the List of Ingredients (provision 9.2.1) for [name of product] for young children, and further discuss the bold text within provision 9.2.2, noting the recommendation to realign with the Infant Formula Standard:

9.2 List of Ingredients

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

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate functional classes names for these ingredients and additives may be included on the label.** ~~[The food additives INS number may also be optionally declared the INS number].~~

1.6.2.4 Declaration of Nutritive Value

At CCFSDU39, the following drafting text for Section 9.3 – Declaration of Nutritive Value for [name of product] for young children was presented in the Agenda Paper (CX/NFSDU 17/39/4 Rev.1). Due to time constraints, this recommendation was not discussed.

9.3 Declaration of Nutritive Value

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

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

- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per ~~{serving size and/or per}~~ 100 kilocalories (or per 100 kilojoules) is permitted.

This recommendation was based on the outcome of two consultation rounds with the 2017 eWG and the widespread support within the eWG to include in the recommendation a proposal to allow for the optional declaration of nutrients per serving. A similar provision was not included for follow-up formula for older infants.

The Chair would like to acknowledge that this preference of the 2017 eWG for a point of differentiation with respect to how the nutritive value should be declared for [name of product] for young children (compared to that for follow-up formula for older infants) was overlooked in the 2018 eWG consultation paper on Scope, Labelling and Definitions. The consultation document instead suggested that the text agreed to for the declaration of nutritive value for follow-up formula for older infants be adopted for [name of product] for young children.

On realising the error, the Chair presented an amendment to the consultation paper on the Scope, Labelling and Definitions for the 2018 eWG to consider. This amendment replaced that included in the original consultation paper, so as to align with the preference of the 2017 eWG for [name of product] for young children and the recommendation within the CCNFSDU39 Agenda Paper (see draft text above). Unfortunately, not all 2018 eWG were aware of the amendment, and some responses reflect that.

eWG views

As mentioned above, eight 2018 eWG respondents did not use the amended form for the Declaration of Nutritive Value proposal which included ~~{serving size}~~ within provision c). All eight respondents did however support the proposed draft text for provisions a) and b).

From those respondents who commented, 25 members (18 CM, 7 CO) used the amended form and supported the Declaration of Nutritive Value text as drafted, including the proposal to adopt ~~{serving size}~~ within provision c).

One CMO commented that they are not convinced by the proposal to add ~~{serving size}~~ to c), as this would be allowed under certain conditions established within the *Guidelines on Nutrition Labelling* (C 2 – 1985).

Conclusion

As there was majority support for provisions a) and b), the Chair recommended these be adopted as drafted; with the use of 'as well as'. Whilst not all eWG respondents commented on the amended version (8 CM) that included ~~{serving size}~~ within provision c), as there was widespread support for its inclusion from those who did use the amended form (25 respondents), it is recommended this text remain within provision c) for further discussion by the Plenary at CCNFSDU40.

Recommendation 14:

That CCNFSDU agree to the following text for the Declaration of Nutritive Value for [name of product] for young children:

9.3 Declaration of Nutritive Value

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

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

1.6.2.5 Date marking and storage instructions

At CCNFSDU39, the Committee agreed to align the date marking and storage instructions for follow-up formula for older infants with the work on date marking finalised by the Codex Committee on Food Labelling (CCFL).

In the 2018 eWG consultation paper, it was suggested that Section 9.4 –Date Marking and Storage Instructions, for [name of product] for young children also adopt this approach and the text agreed to at CCNFSDU39 for follow-up formula for older infants to ensure consistency. The text presented to the eWG was as follows:

9.4 Date Marking and Storage Instructions

9.4.1 (i) The **“Best Before Date” or “Best Quality Before Date”** shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared]. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

(ii) In the case of products requiring a declaration of month and year only, the [date shall be introduced by the words “Best before end <insert date>; or “Best Quality Before end <insert date>].

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

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

eWG views

From those eWG responses that were received on the date marking and storage instructions there was majority support (25 CM, 1 CMO, 4 CO) for adopting the agreed to text for Section 9.4 for follow-up formula for [name of product] for young children (as presented above). Comment was received from three respondents who suggested that the standard could instead state that these products are subject to the date marking and storage instructions according to the *General Standard for the Labelling of Prepackaged Foods* (CXS 1 – 1985) so as to simplify the standard and keep it up-to-date with any future changes that may occur within the General Standard.

Conclusion

In line with the majority view of the eWG and the approach taken for follow-up formula for older infants, the Chair recommends that the date marking and storage instructions text be adopted as drafted, and included within the standard.

Recommendation 15:

That CCNFSDU agree to the following text for Date Marking and Storage Instructions for [name of product] for young children:

9.4 Date Marking and Storage Instructions

9.4.1 (i) The **“Best Before Date” or “Best Quality Before Date”** shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared]. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

(ii) In the case of products requiring a declaration of month and year only, the [date shall be introduced by the words “Best before end <insert date>; or “Best Quality Before end <insert date>].

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

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

1.6.2.6 Information for Use

At CCNFSDU39, the below recommendation for the 'Information for Use' section was presented in the Agenda Paper (CX/NFSDU 17/39/4 Rev.1) for [name of product] for young children.

Based on the views of the 2017 eWG, it was recommended that the text of 9.5.1 be modified, the requirement for information to be included in any accompanying leaflet be deleted, that a prohibition on pictures of feeding bottles be included under Section 9.6 rather than Section 9.5 and that the Committee consider the text contained within the square brackets within provision 9.5.6.

For further detail on 2017 eWG discussions and views, please see the 2017 Agenda Paper ([CX/NFSDU 17/39/4 Rev.1](#)).

9.5 Information for use (as presented at CCNFSDU39)

- 9.5.1** [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [~~Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.~~] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
- 9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula~~ [product] remaining after feeding should be discarded, shall appear on the label.
- 9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product. [~~Pictures of feeding bottles are not permitted on labels of (name of product) for young children.~~]
- 9.5.4** [~~The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.~~]
- 9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
- [9.5.6]** The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] [~~balanced~~] diet.]

Whilst the Committee (at CCNFSDU39) did not discuss this text relating to Information for Use provisions for [name of product] for young children due to time constraints, from the written comments received to the 2017 Agenda Paper (CX/NFSDU 17/39/4 Rev.1), there was majority support for the text as drafted above, with some minor modifications suggested.

With regards to provision 9.5.1, some respondents made suggestions to modify the text to ensure products are prepared with suitable water. It was the view of some that '*potable*' water could replace or accompany the statement that powdered products '*should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation*'.

After much discussion at CCNFSDU39, the following text was agreed to for provision 9.5.1 for follow-up formula for older infants. The 2018 eWG were therefore asked to consider whether this text could also be adopted for [name of product] for young children.

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

Furthermore, the 2018 eWG was asked to consider the remaining text for Section 9.5 for [name of product] for young children, which remains as presented at CCNFSDU39 (as presented above).

As per the approach taken to date, the 'Information for Use' labelling provisions for [name of product] for young children should not be more stringent than that required for follow-up formula for older infants or for infant formula.

eWG views

9.5.1

The majority of the respondents (1 CMO, 20 CM, 2 CO) supported 9.5.1 as it was presented to the 2018 eWG. Five respondents supported the deletion of 'potable' (4 CM, 2 CO) either stating that it is not used in the

equivalent provision in the Infant Formula Standard, or is redundant as it has the same meaning as 'safe' which is already included in the sentence. Three respondents raised their concern that "...or has been rendered safe by previous boiling before feeding" could be misinterpreted to imply that the entire reconstituted product should be boiled prior to feeding and preferred to adopt the wording of the Infant Formula Standard: "...or has been rendered safe by previous boiling for preparation". The need to include a statement that water should be not less than 70°C was raised by three respondents. Two of these additionally suggested further substantial modifications to 9.5.1 including that and a reference to WHO/FAO guidelines on the preparation, storage and handling of powdered infant formula and *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008). They also suggested that the product must be labelled that it is not sterile and could contain Cronobacter (*Enterobacter*) and *Salmonella* and other intrinsic microbial contaminants.

9.5.2

There was close to unanimous support (1 CMO, 23 CM, 4 CO) for 9.5.2 as presented among those that responded. Two CO's suggested the addition of "...shall appear **clearly marked** on the label".

9.5.3

Sixteen respondents (1 CMO, 14 CM, 1 CO) supported 9.5.3 as presented including the deletion of the second sentence that "Pictures of feeding bottles are not permitted on labels of [name of product] for young children." However, several respondents (4 CM, 4 CO) opposed the deletion of the sentence. Four respondents (3 CM, 1 CO) suggested to modify 9.1.3 to: "The label shall carry clear instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions." One CM mentioned that this modification would assist consumers with lower literacy in the appropriate preparation of the product. Two respondents did not consider that the instructions need to be graphic and suggested edits to make graphic instructions optional.

9.5.4

There was a clear majority (1 CMO, 24 CM, 5 CO) for support of 9.5.4. Two respondents considered that 9.5.4 is not needed, one mentioning that it is already covered under 9.5.1 and 9.5.2 and the other considered that a warning on 'health hazards' is not appropriate for a product that is not nutritionally necessary and is consumed in addition to other general purpose foods.

9.5.5

As no recommendations were made to alter the text presented in provision 9.5.5, a number of respondents made no comment and those that did, supported it as it is written. One CM considered it is not needed.

9.5.6

Twenty-one respondents (1 CMO, 18 CM, 2 CO) supported 9.5.6 as it was presented including the removal of the square brackets around 'diversified' and the deletion of 'balanced'. Further two respondents supported 9.5.6 but did not support the deletion of 'balanced'. Four respondents (3 CM, 1 CO) suggested the addition of a statement to the end of the provision '... and that it is not formulated as a substitute for human milk and is not suitable as a sole source of nutrition.' Additional two respondents suggested the addition of only 'and not suitable as a sole source of nutrition'.

Other modifications suggested included the substitution of "...should be used as part of a balanced diet" with "...should not replace a balanced diet" or "...should only be used as a part of a balanced diet", and "The label of [name of product] for young children shall include a statement that the product **is not necessary**, shall not be introduced before 12 months of age and **should may** be used as a part of a diversified diet."

Conclusion

It was the preference of the 2017 eWG to include a prohibition to include pictures of feeding bottles on the label under Section 9.6 Additional Labelling requirements for [name of product] for young children rather than in Section 9.5. It is the recommendation of the Chair in section 1.6.2.7 of this paper that the text in the square brackets which includes that prohibition be included within 9.6.1, and thus the inclusion of such a prohibition in 9.5.3 would be duplication.

In line with the majority view of the eWG, the approach taken for follow-up formula for older infants as well as the approach that the 'Information for Use' provisions or statements for [name of product] for young children need not be more stringent than what is proposed for follow-up formula for older infants, and what is currently required for infant formula, it is the recommendation of the Chair that the Instructions for Use text be adopted as drafted, and included within the standard.

Recommendation 16:

That CCNFSDU agree to the following text for Instructions for Use for [name of product] for young children:

9.5 Information for use

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

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

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

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

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

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

1.6.2.7 Additional labelling requirements

At CCNFSDU39, the below recommendation for the 'Additional Labelling Requirements' section was presented in the 2017 Agenda Paper (CX/NFSDU 17/39/4 Rev.1) for [name of product] for young children:

9.6 Additional Labelling Requirements

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

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

This recommendation was based on the result of two rounds of consultation with the 2017 eWG on the Additional Labelling Requirements for [name of product] for young children. The starting point for discussions was the one 'additional requirement' in the current Follow-up Formula Standard that *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'* and whether this should be retained. The 2017 eWG was asked to consider if any of the additional labelling requirement provisions contained within the Infant Formula Standard were applicable to [name of product] for young children.

As a result of comments to the 2017 first round of consultation and given the differing views on what constitutes a breast-milk substitute, it was decided that the statement, *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'* not be retained in the Standard for [name of product] for young children. Furthermore, it was clarified that this approach does not prejudice or determine whether the product should be considered a breast-milk substitute or not.

At the 2017 second round of consultation, two options for the approach to the Additional Labelling Requirements for [name of product] for young children were presented to the eWG for comment. Option 1 was a more condensed and succinct approach which merged several provisions into one, whereas Option 2 retained individual provisions. It was recommended that a slightly modified Option 1 be presented to the Committee for consideration at CCNFSDU39. Due to time constraints, this recommendation was not discussed.

From the written comments received to the Agenda Paper on this recommendation, there appeared to be general support for the proposal with some minor modifications. It is however noted that some comments received were on the need to be consistent and adopt the 'Additional Labelling Requirements' for follow-up formula for older infants for product for young children. There were also some members who supported a statement around the importance of breastfeeding and others who supported reinstating a provision that these products are not breast-milk substitutes, as per the approach in the current standard. Various comments were received on the text in bold under provision 9.6.2. Views ranged from support for the whole statement, deletion of the whole statement, to requests to remove *'in particular as to the text, images and colours used'* from this provision.

Given the varying written comments received on the 2017 Agenda Paper, 2018 eWG were asked to reconsider the draft text as put forward at CCNFSDU39 for the Additional Labelling Requirements for [name of product] for young children, as already presented above.

eWG views

Sixteen respondents (1 CMO, 13 CM, 2 CO) supported the inclusion of the text *"including pictures of feeding bottles"* in provision 9.6.1. The CMO also suggested that an additional sentence be included that *"the label shall have no text that might recommend or promote bottle feeding of the product"* as it is not generally recommended in its member states to feed young children with bottles with teats. Three respondents supported the deletion of the text in square brackets.

Several respondents (7 CM, 2 CO) stated their view that the Additional Labelling requirements for [name of product] for young children should be the same as those for follow-up formula for older infants and strongly disagreed with that option not having been presented to the eWG for consideration.

Additionally two CM's suggested the addition of selected statements only from the additional labelling requirements for older infants: *'The label shall include a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use'* and *'It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond'* to be included as part of 9.6.1.

Four respondents were of the view that the additional labelling requirement *'The products covered by this standard are not breast-milk substitutes and shall not be presented as such'* in the current Follow-up Formula Standard should be reinstated for [name of product] for young children.

Twelve respondents (1 CMO, 9 CM, 2 CO) supported including all of the text in square brackets in 9.6.2. Thirteen respondents (9 CM, 4 CO) supported the inclusion of **"and to enable consumers to make a clear distinction between them"** but not to include ***"in particular as to the text, images and colours used"*** as that was considered to lack clarity, be open to different interpretations and be a barrier for trade. Two CO's suggested the addition of *'There should be no cross promotion of these products'* to the beginning of provision 9.6.2.

Two respondents suggested the addition of 9.6.3 to read *'The warnings, important notices and instructions for use must occupy no less than 60% of the label space.'*

Conclusion

In line with the majority view of the eWG, it is the recommendation of the Chair that the text in square brackets in 9.6.1 be included. The Chair also recommends that the Committee further discusses the text in square brackets in 9.6.2, taking into account the discussion regarding the equivalent provision for follow-up formula for older infants which is still to be agreed to (see section [1.6.1.2](#) of this paper).

Recommendation 17:

That CCNFSDU agree to the following text for the Additional Labelling requirements for [name of product] for young children and that the Committee further considers whether the text presented within square brackets in provision 9.6.2 be retained with or without the text with strikethrough:

9.6 Additional Labelling Requirements

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

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

1.7 NAME OF PRODUCT FOR YOUNG CHILDREN

As per TOR v, the 2018 eWG was charged with finalising the name of the product for young children.

Based on the comments received during the 2017 eWG consultation rounds, proposals for the name of product for young children was narrowed down. From 2017 eWG comments, it was noted that there was a clear preference to use 'drink' over 'beverage' and for 'formulated' over 'supplementary' within the name. There was also majority support for a name which allows for 'milk-based' or 'plant-based' to be used in the name of the food.

To avoid duplication, it was recommended that the source of protein in relation to the name of the product be covered within Section 9.1 as a separate labelling provision, and for the name to therefore be simple. Section 9.1 permissions (if adopted) will allow for the name of the product to be further qualified with respect to the protein source.

The resultant naming recommendations (for product for young children) put forward to the Committee at CCNFSDU39 for their consideration were:

- Formulated drink for young children
- Young child formulated drink

Noting that the Committee did not get time to discuss the name of product for young children in the Plenary session at CCNFSDU39, from the written comments received to the 2017 Agenda Paper (CX/NFSDU 17/39/4 Rev.1), the Chair noted a clear preference for *Formulated Drink for Young Children* from the two options presented above. A small number of those preferring this name, suggested that the age range be added; *Formulated Drink for Young Children (12 – 36 months)*. Many respondents did not select a preference, or proposed other options. Several suggested *Formula for Young Children* as an alternative option, however the Committee and previous eWG's have already agreed that product for young children should not be considered a 'formula' so as to not confuse product for young children with those suitable for infants.

Other proposals suggested including 'milk-based' or 'plant-based' in the name of the food. As already mentioned, it is proposed that provision 9.1.3 of Section 9.1 – Name of the Food will allow for the name of the product to be further qualified with respect to the protein source as a separate labelling provision, and therefore this should not be duplicated here.

The name *Drink for young children* was also proposed by a small number of respondents.

The Chair notes that previous eWG's have struggled to finalise a name for product for young children with in excess of 30 new or modified proposals provided. It is worth noting that the proposal for provision 9.1.2 within Section 9.1 – Name of Product stipulates the name of product, but also allows for 'any appropriate designation indicating the true nature of the product, in accordance with national {or regional} usage':

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

This approach is in line with that taken in the Infant Formula Standard and the current Follow-up Formula Standard and would allow for variations in the name of the product should the translation of that currently proposed not work for different national contexts, by way of example.

The proposal for the name of product for young children presented to the 2018 eWG for their comment and consideration was; ***Formulated drink for young children***. This proposal reflected a compromise, and took

into consideration the greater support from comments received to the 2017 Agenda Paper for this proposal. Members of the 2018 eWG proposing alternative recommendations were asked to clearly identify why this proposal is not workable as well as provide justification for their changes.

eWG views

From the 2018 eWG responses received, 14 members (10 CM, 4 CO) supported the name proposal **Formulated drink for young children**. A further six eWG members supported a modified name, but all proposals still retained 'formulated' within the name. Examples included; *Formulated Supplementary Drink for young children*; *Formulated Beverage for young children milk-based or plant-based*; *Formulated milk-based (or soy-based) product for young children*; *Formulated milk drink for young children*; *Formulated/supplementary milk-based (or plant-based) drink/beverage for young children*; and *Formulated product for young children*.

Ten eWG members (8 CM, 2 CO) specifically commented that they were opposed to the use of 'formulated' within the name. There were other members who provided alternatives to the proposal presented but who did not specifically comment on the use of the term 'formulated'. Reasons for not supporting 'formulated' included; it contradicts the Committee's decision not to qualify the products as 'specially' manufactured, the name given to this product must be neutral and not imply any benefit, 'formulated' is very similar to 'formula' and caregivers may therefore be misled as to the appropriate age group of consumers for this product.

The preferred alternative name provided was 'Drink for young children' (3 CM, 1 CMO, 1 CO).

Conclusion

The Chair notes the divergent views of the 2018 eWG. They also note the comments received from previous eWG's, and to the 2017 Agenda Paper.

To help guide discussions and for consideration, the Chair notes that within provision 4.1 relating to the name of the food within the *General Standard for the Labelling of Prepackaged Foods* ([CXS 1-1985](#)) it states the following:

4.1.1 The name shall indicate the true nature of the food and normally be specific and not generic.

Furthermore, the Chair recommends that the Committee are cognisant of the Principles that guided the mandatory (core) composition of product for young children, specifically Principle 1; *contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate* and whether this needs to be reflected within the name of the product. It could be viewed that the alternative suggestions for the name such as; *Drink for Young Children*, is too generic and not consistent with provision 4.1.1 of the *General Standard for the Labelling of Prepackaged Foods*, and the principles that guided the mandatory composition.

The Chair therefore recommends that based on the comments received to the 2017 Agenda Paper and the information presented above, the Name of the Product warrants further discussion in the Plenary and propose that 'formulated' be retained within square brackets.

Recommendation 18:

That CCNFSDU consider the following Name of Product (for young children) and further discuss the inclusion of 'formulated' within this name:

[Formulated] drink for young children

1.8 STRUCTURE OF THE STANDARD(S)

In 2014, the eWG agreed that the age range of the current follow-up formula standard, 6–36 months, be retained, however there should be a recognised point of differentiation at 12 months of age due to different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to that of young children. This approach was supported by the Committee at CCNFSDU36 ([REP15/NFSDU, para. 106](#)) where it was agreed to "Review the compositional requirements of the current Standard for Follow-up Formula, 6-36 months with a point of differentiation at 12 months (Sections 3.1-3.3), and propose revised requirements".

In 2016, the Committee at CCNFSDU38 agreed to "Review the Scope and Labelling Sections with a point of differentiation at 12 months, for Section A and Section B of the draft Standard based on the discussions at CCNFSDU38, and propose draft text" ([REP17/NFSDU, para.122](#)).

Consideration of the structure of the standard(s) has not formed part of the ToRs of any of the previous eWGs nor has it been agreed to at the Committee. The 2018 eWG was given the mandate in 2017 by the Committee at CCNFSDU39 to consider the final structure of the standard(s) as per ToR iii: *consider options for the structure of the standard/standards (e.g. whether one standard or two separate standards for the products for the two age groups)*. Given the structure options had not been addressed and discussed previously, the Chair of the eWG decided to consult separately on ToR iii and undertake two rounds of consultation in 2018 to inform the discussion at the Committee meeting (CCNFSDU40).

1st consultation paper on structure

The 1st consultation paper on structure was released in early March 2018 for a four week consultation period. The paper presented four options for the structure of the standard(s) which were pulled together from comments received in previous eWGs on possible options, noting that comments had not been formally sought on the structure before.

The four structure options presented in the 1st consultation paper were:

1. One Standard with two parts (Option 1): Part A covering the composition and labelling aspects of Follow-up Formula for Older Infants, and Part B covering the composition and labelling aspects of [Name of Product] for Young Children.
2. Two separate standards (Option 2): Two stand-alone standards; Follow-up Formula for Older Infants, and [Name of Product] for Young Children.
3. Move Follow-up Formula for Older Infants into the Infant Formula Standard and modify the Follow-up Formula Standard to cover products for Young Children only (Option 3)
4. One standard with four parts which would see the creation of one standard which covers all formula products (Option 4); Infant Formula, Infant Formula for Special Dietary Use, Follow-up Formula for Older Infants and [Name of Product] for Young Children

In addition, the Codex procedural implications for each option were included with the guidance of the Codex Secretariat. The eWG members were asked to consider which of the structure options would be the most suitable considering the technical and compositional aspects of the two products.

The paper asked eWG members to indicate their preferred structure option and provide justification for their preference. Additionally they were asked justify why they did not support the other options described in the consultation paper. Forty responses were received to the 1st Consultation Paper on structure; from 33 CM, one CMO, and six CO. The CMO represents 28 countries.

eWG views

All respondents to the 1st consultation paper agreed that the structure options presented in the paper covered the structure possibilities and no additional approaches were presented for eWG consideration.

There was almost equal support for options 1 and 2 from members of the eWG that responded to the 1st consultation paper. Fifteen respondents (11 CM, 1 CMO, 3 CO) preferred option 1 and in addition two CM mentioned it as their second preferred option. Option 2 was the preferred option of 14 respondents (14 CM) and in addition four respondents (3 CM, 1 CO) mentioned it as their second preferred option. Additionally there were two respondents that supported Option 1 and 2 equally and one member country supported the option that would see the review of the Follow-up Formula Standard completed as soon as possible.

Option 3 was the preferred option of two CM's and an additional three CM's mentioned it as their second preferred option. Option 4 was the preferred option of four eWG members (2 CM, 2 CO) and in addition one CM mentioned it as their second preference.

2nd consultation paper on structure

The 2nd consultation paper on structure summarised the comments received to the first round of consultation on the structure options. Based on the preferences and the justification for and against the four options provided by the respondents to the 1st consultation paper on structure, as well as acknowledging the preference of the eWG members for timely completion of the work, the Chair presented in the 2nd consultation paper the two most supported structure options for further comment and discussion. The Chair noted in particular the strong views of the majority of the eWG members against grouping infant formula, which is a sometimes necessary product and the sole source of nutrition, in the same standard as products that are not necessary and are to be consumed with in addition to complementary foods. More detailed discussion on the justification provided by respondents is discussed below.

The two structure options presented in the 2nd consultation paper were:

1. One Standard with two parts (Option 1)

2. Two separate standards (Option 2)

Thirty-five responses were received to the 2nd Consultation Paper on structure; from 28 CM, one CMO, and seven CO. The CMO represents 28 countries.

eWG views

Option 1 was supported by 13 respondents (1 CMO, 10 CM, 2 CO). Option 2 was supported by 19 respondents (16 CM, 3 CO). Two CO were concerned that the structure options were limited to two without Committee consensus. They did not agree with either option and continued to support option 4 presented in the 1st consultation paper. One CM that supported option 1 had supported option 4 in the 1st consultation round and disagreed with the options 3 and 4 having been left out without consensus having been reached.

Justification for and against each of the structure options

Comments were received in both consultation rounds that articulated that given the Committee has already agreed to review the compositional requirements of the current Standard for Follow-up Formula with a point of differentiation at 12 months, in doing so the Committee has already agreed to one standard with two parts, therefore there is no need to debate the structure further. The Chair would like to reiterate that consideration of the structure of the standard(s) has not formed part of the ToRs of any of the previous eWGs nor has it been agreed to at the Committee. This was discussed at CCNFSDU38; *“In response to concerns that agreement had already been reached on the future form of the standard, the Codex Secretariat noted that it was possible to keep the matter open on the final structure of the standard. Options could include one standard in two parts, two separate standards, or merged with other standards. The Committee supported this position and recognised that it would be possible to see levels of commonality between product ranges as progress was made on the detail of the standard. Continuing to work on an A/B format for the moment would assist the Committee in gaining an understanding of what work could be completed the following year. The Committee agreed on the proposed framework.”* ([REP17/NFSDU, para 67-69](#)). At CCNFSDU39 *“The Committee noted that consideration could be given to the structure of the standard as discussed at CCNFSDU38.”* ([REP18/NFSDU, para 65](#)) and it was included as part of the ToR for the 2018 eWG.

The commonly stated reasons for supporting each of the options are given in the table below. The list is not exhaustive.

Structure option	Comments in support	Comments against
Option 1: One Standard with two parts	<p>Consistent with the approach taken in the Infant Formula Standard; Part A Infant Formula and Part B Formulas for Special Medical Purposes Intended for Infants, both with differing objectives and compositions.</p> <p>In line with the approach that has already been followed for composition and labelling.</p> <p>The two products are conceptually similar and serve as a liquid part of the diversified diet of older infants and young children during the complementary feeding period.</p> <p>This option can accommodate the role of the different products in the diet and different compositions.</p> <p>Both products are breast-milk substitutes.</p> <p>Neither are nutritionally necessary.</p>	<p>Does not clearly address the different roles of the two products for different age groups with differing nutritional requirements.</p> <p>All products for children up to the age of three years are breast-milk substitutes and should therefore sit under one standard.</p> <p>It is not logical to have follow-up formula for older infants, which can be considered to be a breast-milk substitute and product for young children which is not a breast-milk substitute, covered in one standard.</p> <p>Having the two products under one standard gives the impression that the use of one follows the other.</p>

	<p>Approach is consistent with the approach taken in other Codex standards and guidelines such as the <i>Standard for Cereal-Based Foods for Infants and Young Children</i> (CXS-1981) and the <i>Guidelines on Formulated Complementary Foods for older infants and young children</i> (CXG 8-1991) in that both are applicable to two distinct age groups; infants and young children.</p> <p>Would have no procedural implications and would not affect the timeline.</p>		
<p>Option 2: Two separate standards</p>	<p>Approach clearly differentiates and recognises that the two products are very different as to their composition and role in the diet, as well as the different nutritional requirements of older infants and young children.</p> <p>Different names, definitions, purposes, composition and labelling provide the basis for two separate standards.</p> <p>Separate standards would further clarify that infant formula, follow-up formula and product for young children are three different products that also have different compositions and labelling requirements.</p> <p>Allows for distinct labelling to clearly differentiate the products' uses for the intended populations.</p> <p>Other Codex standards and guidelines applicable to the same age groups have only minimal differences in the provisions applying to the different age groups.</p> <p>Would have no procedural implications and would not affect the timeline.</p> <p>Potentially will provide more flexibility in the future when reviewing and updating the standards.</p>	<p>It is not necessary to have separate standards as the role of the products in the diet is similar.</p> <p>Compositional differences are not a justification for two separate standards.</p> <p>Having different standards for the two products gives excess recognition to [name of product] for young children.</p> <p>Both products are breast-milk substitutes and should not be separated into different standards.</p> <p>Would result in too many standards.</p>	
<p>Option 3:</p>	<p>It would be logical to have one standard covering products for 0-12 months and would make sense given that the compositional requirements for follow-up formula for older infants are essentially the same as for infant formula.</p>	<p>It is not logical to separate the product for young children from the others as it is also a breast-milk substitute.</p>	

<p>Move Follow-up Formula for Older Infants into the Infant Formula Standard and a separate Standard covering products for Young Children only</p>		<p>Both options 3 and 4 group infant formula, which is sometimes necessary and a sole source of nutrition, with other products that have been agreed to be unnecessary, and are not a sole source of nutrition.</p> <p>These structure options might cause a delay in completing the review of the Standard.</p>	<p>Moving follow-up formula for older infants under the Infant Formula Standard might result in the product inappropriately being used to feed a 0-6 month old.</p>
<p>Option 4: One standard with four parts which would see the creation of one standard which covers all 'formula' products</p>	<p>All four products are breast-milk substitutes and it is better to have them under one standard to facilitate a better regulatory framework, as well as to prevent the risk of misuse, needless use, and confusion by caregivers.</p> <p>Option does not necessarily involve further delay and the structure should not be determined by the timeline.</p>		<p>Does not recognise the compositional differences of the products, their role in the diet of infants and young children, nor the different nutritional requirements of infants and young children.</p> <p>Including the product for young children in a standard for 'formulas' would inaccurately suggest that it has a complete nutritional profile.</p> <p>Would result in a very large and complicated standard.</p>

Many eWG members (19 CM, 3 CO), in support of either Option 1 or 2 in their response to the consultation papers on structure, cited the need for an approach that allows for clear differentiation of the two products and acknowledges their different role in the diet and their very different compositional requirements. However, the eWG views were divided over which of the structure options they considered best suited for this. Some members considered that Option 1 can accommodate the differences by having two parts to the standard, whereas others considered that the differences would warrant separate standards for each product and that Option 1 does not clearly address the different roles of the two products for different age groups with differing nutritional requirements. The latter was the most commonly mentioned justification for supporting Option 2 (16 CM, 3 CO). Another aspect dividing the views of the eWG members was whether they considered the products to be breast-milk substitutes or not. Some mentioned that they consider both products to be breast-milk substitutes and thus they should not be separated. Contrary view expressed by some was that they consider the product for young children not to be a breast-milk substitute and thus it should have its own standard.

Whilst many respondents shared the view that the products have a different role in the diet, some respondents (1 CMO, 4 CM, 1 CO) were of the view that the products are conceptually similar in being a liquid part of the diversified diet of older infants and young children, and that Option 1 reflects this. Having separate standards for the two products was considered to give excess recognition to [name of product] for young children.

A number of eWG members (1 CMO, 3 CM, 2 CO) considered that Option 1 is in line with the approach that has already been followed for composition and labelling in that there is a point of differentiation at 12 months. However, some (2 CM) also considered that this approach has resulted in products that are distinctly different from one another and maintaining them under one standard is no longer logical. Some (1 CMO, 5 CM, 1 CO) mentioned that Option 1 would be consistent with the approach taken in the Infant Formula Standard which has Part A covering infant formula and Part B covering formulas for special medical purposes intended for infants, both product types with differing objectives and compositions. Option 1 was also mentioned to be consistent with the approach taken in other Codex standards and guidelines such as the *Standard for Cereal-Based Foods for Infants and Young Children* (CXS 74-1981) and the *Guidelines on Formulated Complementary Foods for older infants and young children* (CXG 8-1991) in that both are applicable to two distinct age groups; infants and young children. An opposing view expressed was that the other Codex standards and guidelines applicable to the same age groups have only minimal differences in the provisions applying to the different age groups.

Additionally the eWG members in support of either Option 1 or 2 supported the options as both are within the current mandate of the eWG and would have no effect on the timeline for completing the work. A timely completion of the standard(s) was clearly the preference of all eWG members and many explicitly stated in their response that any unnecessary delay should be avoided. However, one CM and two CO were of the opinion that considerations for the Preamble, scope, definitions and labelling provisions as well as the referencing of WHA resolutions should be prioritised and fully explored before decision on the structure.

Both options 3 and 4 were supported by a small minority of the eWG members that responded to the 1st consultation paper on structure. The options were opposed by many due to them grouping sometimes necessary infant formula products under the same standard as products that have been agreed to be not nutritionally necessary. It was seen essential to keep the infant formula separate to protect its unique nature. Furthermore, it was seen that Option 3 and 4 do not clearly differentiate the different products (infant formula, follow-up formula for older infants and [name of product] for young children).

Conclusion

The Chair notes both the strong preference of the eWG to progress the work without any unnecessary delay and the preference of the eWG members for either one standard with two parts or two separate standards. The Chair therefore recommends that the structure of the standard(s) is further discussed at the Committee meeting with the aim of reaching a consensus decision to facilitate the timely completion of the standard(s).

Recommendation 19.

That CCNFSDU agree to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards.

Appendix II

**PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)
(for comments through CL 2018/62-NFSDU)**

Please note that text presented in *blue italics* reflects the recommendations in Appendix I. The text in *light grey italics* is carried over from CCFSDU39. All other text is as agreed to by the Committee and presented in [REP18/NFSDU Appendix III](#).

Structure of the standard(s) is yet to be decided on. Recommendation 19 in Appendix I is:

‘That CCFSDU agree to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards.’

The below is presented as one standard in two parts as per the framework that has been used to date.

PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

[PREAMBLE]

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

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

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

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

1 [SCOPE]

- 1.1 *This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.*
- 1.2 *This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.*
- 1.3 *Only products that comply with the criteria laid down in the provisions of this section of this Standard [~~should / shall~~] be presented as Follow-up Formula for Older Infants.]*

2 DESCRIPTION

2.1 Product Definition

- 2.1.1 *[Follow-up formula for older infants means a product, ~~specialty~~ manufactured for use as a substitute for breast-milk, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.]*
- 2.1.2 *Follow-up formula [for older infants] is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.*

2.2 Other Definitions

- 2.2.1 The term **infant** means a person of not more than 12 months of age.
- 2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age.

9. LABELLING

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

9.1 The Name of the Product

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

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

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

- a) If [name of animal] milk is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].'
- b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].'
- c) **If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein' or 'Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein'.**

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

9.1.4 A product which contains neither milk nor any milk derivative {shall} ~~{may}~~ be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

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

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate functional classes for these ingredients and additives may be included on the label. {The food additives INS number may also be optionally declared the INS number}.**

9.3 Declaration of Nutritive Value

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

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold {as well as} ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold {as well as} ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 (i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words “Best before end <insert date>; or “Best Quality before end <insert date>].

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

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

9.5 Information for use

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

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

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

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

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

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

~~{9.6}~~ Additional Labelling Requirements

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

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

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

c) a statement that the product should only be used on advice of an {independent} health worker as to the need for its use ~~[including any exception to the age of introduction of 6 months]~~ and the proper method of use.

~~*{d) the statement: 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'}*~~

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

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

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

9.6.2.3 recommend or promote bottle feeding;

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

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

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

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

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

1 SCOPE

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

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

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

2 DESCRIPTION

2.1 Product Definition

2.1.1 **[Name of product] for young children** means a product ~~specifically formulated and~~ manufactured for use ~~as a breast-milk substitute,~~ as a liquid part of the ~~progressively~~ **[diversified]** diet of young children ~~[in order to contribute to the nutritional needs of young children] when nutrient intakes may not be adequate to meet nutritional requirements]-~~

2.1.2 **[Name of product] for young children** ~~[Follow-up formula]~~ is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

2.2.1 The term **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

9. LABELLING

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

9.1 The Name of the Product

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

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

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

a) If [name of animal] milk is the only source of protein[*], the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk {protein}'.

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

c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein' or '[Name of Product] for Young Children Based on [name of plant] protein and [name of animal] milk protein'.

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

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

9.2 List of Ingredients

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

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate functional classes names for these ingredients and additives may be included on the label.** ~~{The food additives INS number may also be optionally declared the INS number.}~~

9.3 Declaration of Nutritive Value

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

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 (i) The "Best Before Date" or "Best Quality Before Date" shall be declared by the day, month and year except that for products with a shelf-life of more than three months, ~~{at least}~~ the month and year ~~{shall be declared}~~. ~~{The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).}~~

(ii) In the case of products requiring a declaration of month and year only, the ~~{date shall be introduced by the words "Best before end <insert date>; or "Best Quality Before end <insert date>}~~.

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

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

9.5 Information for use

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

- 9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula~~ ~~[product]~~ remaining after feeding should be discarded, shall appear on the label.
- 9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product. ~~[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]~~
- 9.5.4** ~~{The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use}.~~
- 9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
- 9.5.6** The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a ~~{diversified}~~ ~~{balanced}~~ diet.]
- 9.6 Additional Labelling Requirements**
- 9.6.1** The label of [name of product] for young children shall have no image, text or representation ~~{,including pictures of feeding bottles,}~~ that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.]
- 9.6.2** Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes[, **and to enable consumers to make a clear distinction between them,** ~~in particular as to the text, images and colours used].~~

Appendix III**List of Participants****Codex Members & Codex Member Organisation**

- | | | |
|------------------------|---------------------|-------------------------------------|
| 1. Argentina | 17. India | 33. Republic of Korea |
| 2. Australia | 18. Indonesia | 34. Russian Federation |
| 3. Austria | 19. Iran | 35. Senegal |
| 4. Brazil | 20. Ireland | 36. Singapore |
| 5. Burkina Faso | 21. Jamaica | 37. South Africa |
| 6. Canada | 22. Japan | 38. Sweden |
| 7. Chile | 23. Kazakhstan | 39. Switzerland |
| 8. China | 24. Malaysia | 40. Thailand |
| 9. Colombia | 25. Mexico | 41. Tunisia |
| 10. Costa Rica | 26. Morocco | 42. United Kingdom |
| 11. Dominican Republic | 27. Nepal | 43. Uruguay |
| 12. Ecuador | 28. The Netherlands | 44. the United States of
America |
| 13. Egypt | 29. New Zealand | 45. Vietnam |
| 14. El Salvador | 30. Norway | |
| 15. The European Union | 31. Peru | |
| 16. France | 32. The Philippines | |

Codex Observers

1. Action Contre la Faim (ACF International)
2. Association Européenne pour le droit de l'alimentation (AEDA/EFLA)
3. Association of Yoghurts & Live fermented milks (YLFA)
4. Comité Européen des fabricants de sucre (CEFS)
5. European Federation of Specialty Food Ingredients Industries (EU Specialty Food Ingredients)
6. European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)
7. European Vegetable Protein Association (EUVEPRO)
8. Global Organization for EPA and DHA Omega-3s (GOED)
9. Helen Keller International (HKI)
10. International Association of Consumer Food Organizations (IACFO)
11. International Baby Food Action Network (IBFAN)
12. International Council on Amino Acid Science (ICAAS)
13. International Council of Grocery Manufacturers Associations (ICGMA)
14. International Dairy Federation (IDF)
15. International Food Policy Research Institute (IFPRI)
16. Institute of Food Technologies (IFT)
17. International Lactation Consultant Association (ILCA)
18. International Special Dietary Foods Industries (ISDI)
19. Specialised Nutrition Europe (SNE)
20. The United Nations Children's Fund (UNICEF)