

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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CL 2022/24/OCS-NFSDU

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TO: Codex Contact Points
Contact Points of international organizations having observer status with Codex

FROM: Secretariat, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme

SUBJECT: Request for comments on the preamble and structure: review of the Standard for follow-up formula (CXS 156-1987)

DEADLINE: 31 August 2022

BACKGROUND

1. The 42nd Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU42) agreed that a discussion paper would be prepared by New Zealand to address the preamble and structure of the revised standard(s).¹
2. The discussion paper is provided in the Appendix to this circular letter.

REQUEST FOR COMMENTS

3. Replies are requested on the questions raised on the structure and preamble in sections 1.3 and 2.4 of the discussion paper, respectively. When providing replies, members and observers should take into account the background to previous discussions and considerations as outlined in the discussion paper.
4. The aforementioned questions are uploaded to the Codex Online Commenting System (OCS): <https://ocs.codexalimentarius.org/>, as per the guidance below.

GUIDANCE ON THE PROVISION OF COMMENTS

5. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.
6. Contact Points of Codex members and observers may login to the OCS and access the document open for comments by selecting "Enter" in the "My reviews" page, available after login to the system.
7. Other OCS resources, including the user manual and short guide, can be found at the following link: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.
8. For questions on the OCS, please contact Codex-OCS@fao.org.

¹ [REP22/NFSDU](#), paras 97 - 99

Appendix

DISCUSSION PAPER ON THE STRUCTURE AND PREAMBLE FOR THE DRAFT STANDARD(S) FOR FOLLOW-UP FORMULA (CXS 156-1987)

(Prepared by New Zealand)

As agreed at CCNFSDU42, this discussion paper has been prepared by New Zealand. It covers the remaining aspects of the review of the *Standard for Follow-up Formula*; structure and preamble and presents questions for consideration and response by members and observers. Responses will be analysed and presented to CCNFSDU43 for further discussion and decision by the Committee in order to complete the work on this review.

1. STRUCTURE

1.1 Background

To facilitate the review of the *Standard for Follow-up Formula* the standard has been presented as one standard with two parts; Section A: Follow up formula for older infants; and Section B: Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children, or Product for young children (hereafter referred to collectively as '*product for young children*') throughout this document.

This approach is the result of the 2014 electronic working group (EWG) recommendation that the age range of the current *Standard for Follow-up Formula*, 6–36 months, be retained, but that 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 recommendation was supported by 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 line with this decision, the CCNFSDU38 agreed to follow the same approach for the scope and labelling ([REP17/NFSDU, para.122](#)).

The Committee has not taken any decisions on the structure of the standard. 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 the 2018 EWG was given the mandate 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)*.

Due to time constraints, the Committee has not considered the work of the 2018 EWG on the structure and the recommendation put forward in the Agenda Paper ([CX/NFSDU 18/40/5](#)).

This paper summarises the EWG consultation on the structure of the standard(s) conducted in two rounds in 2018. It is acknowledged that as most aspects of the standard have now reached completion, previous thinking, justifications and positions may have changed from those presented in the past and thus this CL seeks the views of the Committee on the structure.

1.2 2018 EWG views on structure of the standard(s)

The 1st EWG consultation 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 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 Product for Young Children.
2. Two separate standards (Option 2): Two stand-alone standards; Follow-up Formula for Older Infants, and Product for Young Children.
3. Move Follow-up Formula for Older Infants into the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) (hereafter referred to as 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 Product for Young Children

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 strong and almost equal support for options 1 and 2 with only a few respondents supporting options 3 and 4.

Based on the EWG preferences and the justification provided for and against the four options, only options 1 and 2 as the two most supported structure options, were presented in the 2nd consultation paper for further comment. These two options remained equally supported by the EWG in the 2nd round consultation with no clear majority in favour of either option.

1.2.1 Justification for and against each of the structure options

The commonly stated reasons by the members of the 2018 EWG in support and against each of the structure options are presented in Table 1 in Appendix 1. The table is not exhaustive and is provided for background only. It is acknowledged that views and justifications may have changed given the progress made on the review of the standard(s) since comments were sought in 2018.

Many EWG members, in support of either Option 1 or 2, cited the need for an approach that allows for clear differentiation of the two products and acknowledgement of their different role in the diet and very different compositional requirements. However, the views were divided over which of the structure options were best suited for achieving this. Some members considered that Option 1 (one Standard with two parts) can accommodate the differences by having two parts to the standard, whereas others considered that these differences warrant separate standards for each product. Further, some considered that Option 1 does not clearly address the different role in the diet of the two products which are for different age groups with differing nutritional requirements. The latter was the most commonly raised justification for supporting Option 2 (two separate standards). Another aspect dividing the EWG members was whether they considered the products to be breastmilk substitutes or not. Some mentioned that they consider both follow-up formula for older infants and product for young children to be breastmilk substitutes and thus they should not be separated. Contrary views were expressed by some who considered product for young children not to be a breastmilk substitute and that it should have its own standard.

It is important to note that in the intervening years, the Committee has since agreed (CCNFSDU40) that follow-up formula for older infants is a breastmilk substitute. Consequently, this has been included in the product description (Section 2.1.1 of the Standard). Due to the polarizing views on the definition of product for young children, it was agreed by the Committee at CCNFSDU41 that the standard would remain silent on classifying product for young children as a breastmilk substitute but noted that in some countries they are regulated as such (REP20/NFSDU para 60).

Many 2018 EWG respondents shared the view that the products have a different role in the diet. Some were of the view that the products are conceptually similar in that they are 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 product for young children.

A number of EWG members 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 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 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.

Options 3 and 4 were supported by a small minority of the EWG members that responded to the 1st consultation paper on structure. These options were opposed by many due to them grouping infant formula under the same standard as products that have been agreed to be not nutritionally necessary. Some respondents considered it essential to keep infant formula separate from other formula products to protect its unique nature as being suitable to be the sole source of nutrition. Furthermore, it was the view of some that Option 3 and 4 do not clearly differentiate the different products (infant formula, follow-up formula for older infants and product for young children).

1.2.2 2018 EWG recommendation

The EWG recommendation put forward to CCNFSDU40 was for the Committee to further discuss the structure of the standard(s), noting the preference of the EWG for either one standard with two parts or two separate standards. This recommendation was not discussed at CCNFSDU40 due to time constraints.

1.3 Questions

The responses to the questions presented in this discussion paper will be analysed and presented to CCNFSDU43 for consideration.

1. Now that the standard has been completed, please indicate your preferred structure approach and clearly state why you do, or do not, support each option:
 - a. One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.
 - b. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children.
 - c. Can support either approach.
 - d. Support a different structure approach – please describe the approach and provide your justification.
2. Do you have any further comments on the structure?

2. PREAMBLE

2.1 Introduction

The concept of a Preamble was first raised at CCNFSDU38 (in 2016) where the Committee noted that it could include a reference to WHO/WHA documents (rather than references be included as part of the Scope).

Whilst a decision has yet to be taken on the Preamble, discussions have been had at previous meetings as to what a Preamble should or should not include, notably relating to the need to reference WHO/WHA documents.

The Codex Procedural Manual does not provide guidance on the purpose of a Preamble and what it should include. The *Format for Codex Commodity Standards* contained within the Procedural Manual does not require a Preamble section.

Any country can use Codex standards as they see fit, Codex standards being voluntary in nature. Codex standards do however serve in many cases as a basis for national legislation. In terms of the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade (TBT), if a dispute arises, Codex standards are an important reference point for the dispute settlement mechanism. Note that the preamble, as well as any annexes or appendices, are an integral part of a Codex standard and contribute to the entire content of the standard.

2.2 Background

In 2017, the EWG considered WHO/WHA referencing within the *Standard for Follow-up Formula*. Due to polarised views within the EWG for and against referencing WHO/WHA documents, the EWG Chair engaged with the Codex Secretariat and WHO to progress this issue and find a workable solution. The result was the concept of a Preamble that could include reference to relevant documents. The intent was that this approach to the Preamble would replace the need to list or reference specific documents or resolutions within different sections of the Standard itself as the Preamble is applied to the Standard as a whole.

The [Agenda Paper](#) at CCNFSDU39 (CX/NFSDU 17/39/4 Rev.1) put forward Recommendation 9 which included draft text for a Preamble statement (replicated below) that included specific reference to relevant WHO documents and WHA resolutions. Text from the Codex *Statement on Infant Feeding* CAC/MISC 2-1976 was used as the starting point for drafting Recommendation 9. At CCNFSDU39, there was some inconclusive discussion on the Preamble, however the Committee agreed to keep this section in brackets for further discussion at CCNFSDU40.

Further, the Chair noted that several fundamental questions needed to be answered on whether to have specific references to WHA resolutions and WHO guidelines or whether to have a more general reference; that some of the WHA resolutions went beyond the mandate of Codex and therefore were inappropriate to reference; and whether guidance from the CCEXEC or CAC might be needed before the wording of the Preamble could be refined.

Recommendation 9 as per CX/NFSDU 17/39/4 Rev.1

The Codex Alimentarius Commission acknowledges the need to [protect and support /recognize] breast-feeding 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 (CODEX STAN 72 – 1981).

In 2018, CCEXEC75² (and reaffirmed by CCEXEC77)³ provided advice on references to WHO/WHA documents in the draft Follow-up Formula Standard:

- 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.

Codex Members are encouraged to familiarise themselves with [CRD 2](#) from CCNFSDU42 when considering the questions presented in this paper. The CRD was prepared as a way of providing background to the Committee on the evolution of the scope, definition and labelling sections of the *Standard for Follow-up Formula*. It presents a timeline of discussions, considerations and decisions relating to how relevant concepts and technical guidance in WHO/WHA documents have informed the labelling and other provisions within the draft standard(s). The table contained within CRD 2 illustrates how during the review of the *Standard for Follow-up Formula*, the EWG and Committee has followed the advice of CCEXEC75, specifically recommendations a), c), and elements of d).

This CL includes several questions. The responses to these will assist the Committee in its deliberations on what is the purpose of the Preamble, what it should include, is it linked to the structure of the standard(s), is it needed at all, and what might the drafting contain?

2.3 Approaches to a preamble in other CCNFSDU texts

Different approaches have been taken to the Preamble for different Codex standards. The current *Standard for Follow-up Formula* ([CXS 156–987](#)), the *Standard for Processed Cereal-based Foods for Infants and Young Children* ([CXS 74–1981](#)), and the *Standard for Canned Baby Foods* ([CXS 73–1981](#)) do not have a Preamble. The *Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* ([CXS 72–1981](#)) has a very simple Preamble which states that the Standard is divided into two sections; Section A refers to Infant Formula, and Section B deals with Formulas for Special Medical Purposes Intended for Infants.

The most recently drafted Preamble was that for the *Guidelines for Ready-to-Use Therapeutic Foods*. The decision taken at CCNFSDU42 ([REP22/NFSDU](#) paras 102 – 109) was to keep the Preamble simple yet refer to the basic composition, the target age group, and that RUTF is a recommended option for the dietary management of severe acute malnutrition.

In relation to the discussion on the revised Preamble for the *Guidelines for Ready-to-Use Therapeutic Foods* that was had at CCNFSDU42, the Chairperson clarified that the Preamble should set the scene by providing the overall context but does not specify any product requirements which are found within the main body of the 'Guidelines'. The Codex Secretariat further clarified that the Preamble should not address matters outside the scope of Codex and that discussion on the Preamble should be guided by the *General Principles of the Codex Alimentarius*. The Committee was advised of Section 3 of these Principles: *Nature of Codex Standards* which states that;

Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

Thus, issues not addressed in the 'Guidelines' were still subject to countries' laws and requirements.

² REP18/EXEC2-Rev.1, paras 12 - 18

³ REP19/EXEC2, para. 11

The advice of CCEXEC75 on referencing WHO/WHA documents, and CCEXEC78 on references to other standards setting organisations was taken into account when revising the RUTF Preamble. This was to ensure a minimum number of references that would require lifelong monitoring.

2.4 Questions

Codex Members are encouraged to think about the link to the structure and the need to ensure any Preamble text is not in conflict with, or more stringent than, the composition and labelling aspects of the Standard(s) (as these have already been agreed by the Committee) when responding to the questions below.

If there is to be a Preamble, members are reminded that as per the guidance provided by the CCNFSDU Chair for the RUTF, Preamble text should set the scene by providing the overall context but does not need to specify any product requirements which are found within the main body of the Standard(s).

The responses to the questions presented in this discussion paper will be analysed and presented in a paper for CCNFSDU43.

3. Do you think this Standard(s) requires a Preamble? Yes/No
4. If so, what is the purpose of having a Preamble for this Standard(s)? Please provide rationale and justification for your thinking.
5. What detail should the Preamble contain? Please provide rationale and justification for your thinking.

(for information)

Table 1. Structure options and comments in support and against each option received from 2018 EWG members

Structure option	Comments in support	Comments against
<p>Option 1: One Standard with two parts</p>	<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>Approach is consistent with the approach taken in other Codex standards and guidelines such as the Standard for Cereal-Based Foods for Infants and Young Children (STAN 74-1981) and the Guidelines on Formulated Complementary Foods for older infants and young children</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>(CAC/GL 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>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 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>Potentially will provide more flexibility in the future when reviewing and updating the standards.</p>		
<p>Option 3: Move Follow-up Formula for Older Infants into the Infant Formula Standard and a separate Standard covering products for Young Children only</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>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>It is not logical to separate product for young children from the others as it is also a breast-milk substitute. 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. Option does not necessarily involve further delay and the structure should not be determined by the timeline.</p>	<p>These structure options might cause a delay in completing the review of the Standard.</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. Including product for young children in a standard for 'formulas' would inaccurately suggest that it has a complete nutritional profile. Would result in a very large and complicated standard.</p>