

Review of the Follow-up Formula Standard (CODEX STAN 156 – 1987)

2018 2nd Consultation Paper – STRUCTURE

RESPONSE from IACFO

Responses due Friday 27 July 2018

Submitters are asked to respond to the questions at the end of this Consultation Paper by commenting in the text boxes. Only one response per Codex Member or Codex Observer is permitted. Please post your response on the Codex on-line platform by the due date. We ask that eWG members do not use the platform to comment on and critique individual submissions when these have been posted. This document is a consultation paper which may be used for the purpose of internal consultation, but not for full publication.

The responses to this consultation paper will be used to inform the Agenda paper for CCNFSDU40.

1. INTRODUCTION

Still outstanding in the review of the Follow-up Formula Standard is a decision on the final structure of the standard. This in turn will inform the name of the standard based on what products are covered. The 2018 eWG has been given the mandate to consider the structure and as per the consultation approach communicated earlier, the Chairs decided to consult separately on Terms of Reference (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)* and undertake two rounds of consultation.

In addition a separate consultation paper was written to address the outstanding aspects relating to scope, labelling and definitions. The consultation period for that paper closed on June 13th and the responses received will inform the Agenda Paper for 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 and discussions with the Chairs 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)
2. Two separate standards (Option 2)
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)

For more detailed description of each structure option please see Appendix 1 to this paper.

In addition, the Codex procedural implications for each option were included with the guidance of the Codex Secretariat, however this was included for information and should not significantly influence a preferred structure. 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.

Forty responses were received to the 1st Consultation Paper on structure; from 33 Codex Member Countries, one Codex Member Organisation, and 6 Codex Observers. The Codex Member Organisation represents 28 countries.

Responses to the 1st Consultation paper on Scope and Labelling were received from the following eWG members:

CODEX MEMBER COUNTRIES AND MEMBER ORGANISATIONS				
Argentina	Australia	Brazil	Burkina Faso	Canada
Chile	China	Colombia	Costa Rica	Dominican Republic
Egypt	European Union	France	India	Indonesia
Iran	Japan	Malaysia	Morocco	Nepal
The Netherlands	New Zealand	Norway	Peru	Philippines
Russian Federation	Senegal	Singapore	South Africa	Sri Lanka
Switzerland	Thailand	USA	Vietnam	
CODEX OBSERVERS				
EUSFI	HKI	IACFO	IBFAN	ISDI
UNICEF				

The Chairs note that two of the Codex Member Countries (France and the Netherlands) are also members of the Codex Member organisation (European Union) and their responses were supporting that of the Codex Member Organisation. Their responses are acknowledged by the Chairs and not counted separately in the numbers presented for each of the options.

2nd consultation paper on structure

This 2nd consultation paper on structure summarises the comments received to the first round of consultation on the structure options, as well as seeks further comment and discussion on the preferred options.

For the purpose of this paper, the following abbreviations have been used: CM (Codex Member), CMO (Codex Member Organization), and CO (Codex Observer).

2. BACKGROUND

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 CCNFSU36 ([REP15/NFSUJ, para. 106](#)) where they 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 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](#)).

The approach agreed to by the Committee to differentiate product for older infants from that for young children in terms of composition and labelling, has created two distinctly different products. As per ToR iii, the mandate of the 2018 eWG is to consider how best to present these products within the structure of a standard or standards.

Current timeline

- Essential composition for Follow-up Formula for Older Infants and [Name of Product] for Young Children to Step 5 for adoption by CAC41 in 2018.
- Adoption of the draft standard at Step 5 in 2019 with a view to final adoption and completion of work by CAC in July 2020.

3. STRUCTURE OPTIONS

eWG views

The members of the eWG were asked to indicate their preferred option of the four options described in the consultation paper. In addition they were asked whether there are other options that they would prefer that are not captured in the paper. All members of the eWG that responded agreed that the structure options presented in the 1st consultation paper covered the possibilities and no additional ones were mentioned for the eWG to consider. A timely completion of the standard(s) was clearly the preference of all eWG members and many stated that any unnecessary delay should be avoided.

There was almost equal support for options 1 and 2 from members of the eWG that responded to the 1st consultation paper. Fifteen members (11 CM, 1 CMO, 3 CO) preferred option 1 and in addition 2 CM mentioned it as their second preferred option. Option 2 was the preferred option of 14 member countries and in addition four members (3 CM, 1 CO) mentioned it as their second preferred option. There were two members (1 CM, 1 CO) 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 eWG members (2 CM) and an additional three members (3 CM) mentioned it as their second preferred option. Option 4 was the preferred option of in total four eWG members (2 CM, 2 CO) and in addition 1 member country mentioned it as their second preference.

Comments on Option 1

Those that supported option 1 mentioned that the approach is consistent with that taken in the Infant Formula Standard, the direction that has already been followed for composition and labelling, and in line with what was agreed by the Committee in 2016 (see Background). It was mentioned that Option 1 reflects that the products are conceptually similar and neither are nutritionally necessary. On the other hand a reason given for supporting Option 1 was that this approach can accommodate the role of the different products in the diet by having two parts to the standard. Four eWG members (3 CM, 1 CO) noted that Option 1 would also 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 (STAN 74-1981) and the Guidelines on Formulated Complementary Foods for older

infants and young children (CAC/GL 8-1991) in that both are applicable to two distinct age groups; infants and young children.

Option 1 was also supported by many because it has no procedural implications and thus would not affect the timeline. One observer mentioned that Option 1 is preferred as Option 2 is seen as carrying the risk of the work on product for young children being abandoned and this is considered unacceptable.

The most frequently mentioned reason given for not supporting Option 1 was that it does not clearly address the different roles of the two products for different age groups with differing nutritional requirements. Some members did not support Option 1 as they consider that all products for children up to the age of three years to be breast-milk substitutes and that they should therefore sit under one standard. A comment was also received that the format of Option 1 is not user friendly.

Comments on Option 2

Option 2 was mentioned to clearly differentiate and recognise the two very different products as to their composition and role in the diet. Many of the members supporting this option were of the view that follow-up formula for older infants is a breast-milk substitute and nutritionally complete whereas product for young children is neither, and that having separate standards would further clarify that infant formula, follow-up formula and product for young children are three different products.

Option 2 was also mentioned to fit within the terms of reference of the eWG, result in no time delay, potentially provide more flexibility in the future when reviewing the standards, and make the standards more user friendly compared to the other structure options.

Reasons given by those eWG members not supporting option 2 included that it is not necessary to have separate standards as the role of the products in the diet is similar and that a separate standard for product for young children would give excess recognition to the product for young children. Some considered that both products are breast-milk substitutes and should not be separated into different standards. One member country also mentioned that this option would result in too many standards.

Comments on Option 3

Reasons mentioned for supporting Option 3 were that it would be logical to have one standard covering products for 0-12 months and the structure would make sense given that the compositional requirements for follow-up formula for older infants are essentially the same as for infant formula. The option was seen as workable provided that it wouldn't delay the completion of the standards.

Reasons mentioned for not supporting Option 3 were that follow-up formula for older infants and infant formula have different nutritional purposes and should not be combined under one standard. It was seen essential to keep the Infant Formula Standard separate as infant formula is necessary when infants can't be breastfed whereas follow-up formula is not a necessary product. It was also mentioned that it would not be logical to separate the product for young children from the others as the respondent considered it to also be a breast-milk substitute. On the other hand some members expressed concern that 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.

Additionally members referred to the procedural implications that could cause a delay in completion of the work. Some considered that Option 3 would not add any value over Option 1 or 2 and some were concerned that Option 3 could result in standard for product for young children being abandoned.

Comments on Option 4

The respondents that supported Option 4 considered that all four products are breast-milk substitutes and considered it 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. It was also considered that Option 4 does not necessarily involve further delay and that the structure should not be determined by the timeline.

Several members mentioned that they did not support Option 4 because the products differ significantly from each other in terms of their composition and their role in the diet of infants and young children. The option was not seen to recognise the different nutritional requirements of infants and young children. Additionally some members considered that Option 4 does not make the distinction between sometimes necessary (infant formula) and unnecessary products. Concern was also raised that having the product for young children under a standard for 'formulas' would inaccurately suggest that it has a complete nutritional profile.

Other reasons mentioned for not supporting Option 4 included that it is complicated, would not bring any added value, would result in a very large standard, would cause unnecessary delay and may jeopardise the completion of the review of the Follow-up Formula Standard.

Additional comments

Additional comments provided included the suggestion for CCNFSDU to possibly propose revision of the Infant Formula Standard to cover product for infants 0-6 months only and to avoid any overlap in the age range with follow-up formula for older infants 6-12 months.

One CM suggested choosing the option (1 or 2) that would result in timely completion of the review of the Follow-up Formula Standard and at a later stage the Committee could consider whether all standards for milk products for 0-3 years could be merged, including a revision of the Infant Formula Standard.

In addition one member country and two observers 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.

Chairs proposal

The Chairs note the strong preference of all members to progress the work without any unnecessary delay. Based on the preferences of the eWG, the Chairs propose that options 1 and 2 continue to be considered as the possible approaches for the structure of the standard(s). Many eWG members in support of either option 1 or 2 cited the need for an approach which allows for clear differentiation of the two products and acknowledgement of the different role in the diet and very different composition of each. In addition both of these options are within the current mandate of the eWG and would have no effect on the timeline for completing the work.

Both options 3 and 4 were supported by a small minority of the eWG members and 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. Furthermore, it was seen that these approaches do not clearly differentiate the different products (infant formula, follow-up formula for older infants and [name of product] for young children). Therefore the Chairs propose that these options are no longer considered.

Please see the questions for the eWG to consider on the following page.

4. QUESTIONS FOR SUBMITTERS

QUESTION 1:

Please indicate your preferred option, from the two remaining options presented for the structure of the standard(s) for Follow-up Formula for Older Infants and [Name of Product] for Young Children.

Please provide justification for your preference.

Option 1: One standard with two parts

Option 2: Two separate standards

Justification:

IACFO does not agree with Option 1 or Option 2 – see answer to Question 2

QUESTION 2:

Do you have any further comments on the structure?

RESPONSE structure of the standard(s) for Follow-up Formula for Older Infants and [Name of Product] for Young Children.

IACFO supports IBFAN's position. IACFO is concerned that the decision to limit the structure of the standard(s) for Follow-up Formula for Older Infants and [Name of Product] for Young Children to Option 1 and 2 does not have Committee consensus.

IACFO is of the opinion that the preamble, scope, definitions and labelling provisions for the follow-up formula for older infants and the follow-up formula for young children need to be determined before the structure is decided.

This would clarify the pros and cons of decisions regarding the structure.

We see no reason why substantial changes need to be made to the IF standard (other than to the scope and the overarching preamble) in order to accommodate all four sections into one standard. Having multiple standards for products that all function as breastmilk substitutes and all need similar, careful regulation and monitoring as to composition, safety, labelling and marketing, will create many risks and opportunities for misunderstandings by governmental regulators.

IACFO repeats its opinion that it is better to have all the breastmilk substitutes under one standard to ensure that all the products are labelled and marketed, including the prohibition on cross branding, to prevent the risks of misuse, needless use and confusion.

We are concerned that the way the 4 options have been presented in the consultation papers places unjustified emphasis on the disadvantages

of Option 4 - the option that IACFO and IBFAN consider the safest option to protect child health. Safeguarding child health and limiting the harmful labelling and marketing of these products should be the highest priority for Codex.

We do not believe that the process should be determined by the timeline, nor do we believe that option 4 would necessarily involve further delay. If it were to be submitted to CAC after the scope, definitions and labeling are determined, there should be no reason why the proposed timeline cannot be met.

The important consideration for CCNFSDU is to give full discussion to the preamble and the inclusion of the International Code and subsequent relevant WHA resolutions including the WHA 69.9 and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children, and the Global Strategy for Infant and Young Child Feeding, with the aim of ensuring that breastfeeding, appropriate infant and young child feeding and optimal child health, is not undermined. These considerations should be prioritized and fully explored before the discussion on structure.

Consultation Copy

Appendix 1

Summary of the different structure options presented to the eWG for consideration

Option	Infant Formula Standard	Follow-up Formula Standard	Procedural Implications
1	Section A: IF Section B: IFSMP	Part A: FUFOI Part B: YC	No procedural implications.
2	Section A: IF Section B: IFSMP	Split the current Follow-up Formula Standard to create two new stand-alone standards. Standard for FUFOI Standard for YC	No procedural implications. No need to request new work to create two separate stand-alone standards. Inform CAC of the decision to have two stand-alone standards and provide the rationale for this approach. This could be seen as consequential. This option would not impact on the timeline.
3	Section A: IF Section B: IFSMP Section C: FUFOI	FUFOI moved out of current Follow-up Formula Standard and into the Infant Formula Standard. Follow-up Formula Standard modified to cover YC only.	If FUFOI can be moved in to the IF Standard with some minor adjustments to the Standard, this could be considered consequential. If this approach required substantial changes to parts of the IF Standard, this approach would require approval from CAC for new work. This option might have implications for meeting the timeline.
4	Section A: IF Section B: IFSMP Section C: FUFOI Section D: YC	Revoked	If this approach required substantial changes to parts of the IF Standard, this approach would require approval for new work. A project document would need to be prepared for new work on revision of the IF Standard. CAC would need to be informed that work on the FUF Standard was being discontinued. Once work on the IF Standard was completed, the current FUF Standard should be revoked. This option would also mean that a new timeline for the work would need to be set.

IF: Infant Formula

IFSMP: Formulas for Special Medical Purposes Intended for Infants

FUFOI: Follow-up Formula for Older Infants

YC: [Name of Product] for Young Children