



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

**Forty-second Session**

**Virtual**

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**REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987):**

**EWG-Report on draft product definition of drink/product for young children with added nutrients or drink for young children; and Nitrogen to protein conversion factors**

*(Prepared by the electronic working group led by New Zealand, France and Indonesia)*

Codex members and Observers wishing to submit comments on the recommendations in this document should do so as instructed in CL 2021/54/OCS-NFSDU available on the Codex webpage/Circular Letters:

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

## **1 INTRODUCTION**

At the 41st session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU41), the Committee agreed to continue work on the revision of the *Standard for Follow-up Formula (CXS 156-1987)* and to:

Re-establish the EWG chaired by New Zealand and co-chaired by France and Indonesia and working in English to:

- a. Finalise the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children', by reviewing the outstanding text '[which may contribute to the nutritional needs of young children]';
- b. Consider the linkages and impact between the definition and name for 'Drink/Product for young children with added nutrients' and 'Drink for young children'; and
- c. Consider the report and options provided by JEMNU in the Nitrogen to protein conversion factors for soy-based and milk-based ingredient used in infants and follow-up formula, and to what extent it needs to be considered for the revision of the draft standard/s for follow up formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children'.

Since CCNFSDU41, the scope, definition and labelling of 'Drink/Product for young children with added nutrients' and 'Drink for young children' have been adopted at Step 5 by CAC43 and subsequently a Circular Letter was issued for comments at Step 6 ([CL 2021/03/OCS-NFSDU](http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/)).

CCFL46 will consider the labelling provisions for 'Drink/Product for young children with added nutrients' and 'Drink for young children' as well as the labelling provision 9.6.5 for follow-up formula for older infants at its September 2021 meeting.

### **1.1 Conduct of the Electronic Working Group (EWG) 2020**

The EWG (list of the 64 participants is presented in APPENDIX II

LIST OF 2020 EWG PARTICIPANTS) has considered one consultation paper since CCNFSDU 41. The consultation paper was posted on the Codex online platform in April 2020 for a ten-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

CL: Circular letter

JEMNU: Joint FAO/WHO Expert Meeting on Nutrition

NCF: Nitrogen Conversion Factor

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

The full discussions and recommendations of the EWG are presented in Appendix I.

## 1.2 Conclusions

### Definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children' (TOR a and b)

The Chair of the EWG has used feedback from the 2020 EWG consultation to prepare this Agenda Paper. Additional comments submitted specifically on the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children' in response to the Circular Letter issued for comments at Step 6 ([CL 2021/03/OCS-NFSDU](#)) have also been considered and included in this report.

The EWG Chair is of the view that based on the consolidated responses received to both the EWG consultation paper and the additional comments received in response to the CL, it is unable to put forward a recommendation on the definition for Committee agreement at CCNFSDU42.

It is therefore the recommendation of the EWG Chair that CCNFSDU42 consider the EWG comments on the definition and the responses to the CL, and focus discussions on whether the text in the square brackets within the definition be accepted or deleted, and that the Committee do not consider further options for modifying the text or an alternative definition.

### Nitrogen to protein conversion factors (TOR c)

The EWG was nearly unanimous in its view that the NCF for follow-up formula for older infants and 'Drink/Product for young children with added nutrients', 'Drink for young children' cannot be considered in isolation from infant formula. The EWG majority view was also that prior to considering a change to the NCF a decision needs to be taken whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein before considering the most appropriate NCF.

As the mandate of the work on the review of the Standard for Follow-up Formula does not extend to infant formula, and noting the EWG support that the work on the review of the Standard for Follow-up Formula should not be delayed by the consideration of the primary aim of determining protein content, the Chair recommends that the NCF of 6.25 is retained in the standard(s) and that NCF is not considered further as part of the work on the review of the Standard for Follow-up Formula.

Appendix I contains two recommendations covering the terms of reference for the EWG for the Committee's consideration at CCNFSDU42

## 1.3 Recommendations

CCNFSDU is invited to agree:

- (i) On one of the two options presented in Recommendation 1, Appendix I; and
- (ii) That the NCF of 6.25 is retained in the standard(s) for Follow-up Formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children' (Recommendation 2, Appendix I).

## APPENDIX I

## DISCUSSION AND RECOMMENDATIONS OF THE EWG

## 1 DEFINITION OF 'DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS' AND 'DRINK FOR YOUNG CHILDREN'

At CCNFSDU41 there was considerable discussion and debate around the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children'. Discussion centred on whether product for young children should be defined as a breast-milk substitute, or not (para 54 – 62 of [REP20/NFSDU](#)).

In order to reach consensus the Committee agreed on a revised definition that followed the guidance of previous EWGs, that Codex remain silent on the issue of whether the product was or was not to be described as a breast-milk substitute but with the addition of a footnote to state that these products are regulated as breast-milk substitutes in some countries.

The 2020 EWG was tasked with reviewing the outstanding text [*which may contribute to the nutritional needs of young children*] contained within the definition. The text already agreed to at CCNFSDU41 was not being discussed as the EWG was only charged with reviewing the outstanding text in square brackets as per the terms of reference.

## 1.1 Background

The definition of product for young children has been consulted on in previous EWGs (2017 and 2018), with multiple proposals put forward including the text currently contained within the square brackets. There was an exchange of views on the definition at CCNFSDU39 and CCNFSDU40 but due to time constraints no decision was taken.

At CCNFSDU41 the Committee discussed the definition and agreed to the following text, noting the remaining sentence in square brackets which was the focus of the 2020 EWG consideration:

***Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [*which may contribute to the nutritional needs of young children*]***<sup>1</sup>

<sup>1</sup> *In some countries these products are regulated as breast-milk substitutes.*

## 1.2 Principles for mandatory composition

To further assist with the consideration of how '*Drink/Product for young children with added nutrients*' and '*Drink for young children*' is defined, the EWG was reminded of the principles (as agreed to by the Committee) that guided the proposed mandatory (core) composition of this product and which are replicated below (see para 72, [REP17/NFSDU](#)).

**Principles for the mandatory (core) composition of product for young children**

Evidence to support:

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 milk, and if appropriate breastmilk, 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.

Recognising that whilst these products are not nutritionally necessary in the diets of all young children, they can make a positive nutritional contribution to the diet in situations where consumption of some key nutrients is inadequate, and to ensure contribution of adequate amounts of key nutrients from cows' milk, and if appropriate breastmilk, where such nutrients are key contributors to the diet of young children (as per the principles for the mandatory composition of product for young children).

Based on this premise, the Committee agreed to the mandated composition to be the following key nutrients from cows' milk: riboflavin, vitamin B12, and calcium, in addition to vitamin A, vitamin D, iron, vitamin C (to aid iron absorption) and zinc which were deemed from global data collection to be widely inadequate in the diets of many young children.

This mandatory composition differentiates this product from cows' milk and other manufactured drinks/products for young children.

### 1.3 EWG consideration of the definition

As per the Procedural Manual<sup>1</sup>, the Description section of Codex commodity standards should contain the definition of the product or products.

The Chair of the EWG thought it may prove helpful for the EWG to consider the elements contained within the product definition of other foods for infants and young children, and how they are 'described'. In addition to the product definitions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)* and the agreed definition for follow-up formula for older infants, it was thought the product definition in the *Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991)* may offer assistance with discussions on the definition as these foods are also not considered nutritionally necessary in the diet of young children.

*Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.*

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

*Formulated Complementary Foods for Older Infants and Young Children means foods that are suitable for use during the complementary feeding period. These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities.*

All three definitions above include a description of the intended role in the diet that these products play, and the purpose that they have been manufactured for.

Further, whilst there are several name options, there is to be one definition. The definition must therefore be considered in isolation and should be relevant regardless of what naming convention countries choose to use. The EWG was therefore asked to give consideration to how product for young children (regardless of the name) should be described, and what elements should be included in the definition, noting that the definition is a regulatory tool and is not required on the label.

### 1.4 EWG views on the purpose of the definition

The EWG was asked the following question:

What is the purpose of the definition for 'Drink/Product for young children with added nutrients' and 'Drink for young children', and what critical elements should form part of the definition?

In their response many (10 CM, 3 CO) referred to the Procedural Manual which states in relation to the description of the product in a commodity standard:

*"This section should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which it is derived and any necessary references to processes of manufacture. It may also include references to types and styles of product and to type of pack. There may also be additional definitions when these are required to clarify the meaning of the standard."*

However the respondents' interpretation of the text in the Procedural Manual differed with some being of the view that it does not require the definition to cover the role or purpose of the product in the diets of young children and others that it should.

Several respondents (18 CM, 1 CMO, 3 CO) mentioned that the definition should include the purpose the product has been manufactured for and description of the intended role of the product in the diet. A number of these (12CM, 2 CO) also mentioned that the definition should differentiate the product from other drinks/products for young children, many noting that the differentiating factor are the mandatory nutrients.

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<sup>1</sup> Section II – Elaboration of Codex Texts: Format for Codex Commodity Standards

Additional comments included that the definition should provide sufficient information for regulators and industry to correctly apply the standard; that it be as simple and clear as possible; and that the definition should not in any way idealise and promote these products or infer that the products would be necessary.

### 1.5 Definition proposals

The Chair of the EWG presented the following three proposals for the outstanding text within the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children' for EWG consideration.

OPTION	PROPOSAL
<b>1</b> Accept text in [ ]	<b>Drink/product for young children with added nutrients or Drink for young children</b> means a product manufactured for use as a liquid part of the diversified diet of young children <del>[which may contribute to the nutritional needs of young children]</del> <sup>1</sup> <sup>1</sup> In some countries these products are regulated as breast-milk substitutes.
<b>2</b> Delete text in [ ]	<b>Drink/product for young children with added nutrients or Drink for young children</b> means a product manufactured for use as a liquid part of the diversified diet of young children <del>[which may contribute to the nutritional needs of young children]</del> <sup>1</sup> <sup>1</sup> In some countries these products are regulated as breast-milk substitutes.
<b>3</b> Modified from <a href="#">CXG 8-1991</a>	<b>Drink/product for young children with added nutrients or Drink for young children</b> means a product manufactured for use as a liquid part of the diversified diet of young children <del>[which may contribute to the nutritional needs of young children]</del> <b>[These products provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities.]</b> <sup>1</sup> <sup>1</sup> In some countries these products are regulated as breast-milk substitutes.

### 1.6 EWG views on definition proposals

The EWG was asked to select a preferred option (from those presented above) for the outstanding text within the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children' and provide justification for their response. Comment was not sought on the text already agreed to at CCNFSDU41.

Of the 41 EWG respondents (33 CM, 1 CMO, 7 CO) who selected a preferred definition, 15 (12 CM, 3 CO) supported Option 1 put forward in the consultation paper and 19 (14 CM, 1 CMO, 4 CO) supported Option 2. Seven respondents (7 CM) supported Option 3, or a modification of this.

Many in support of Option 1 were of the view that retaining the text in square brackets helps to differentiate these products from other beverages for young children and works to adequately describe the purpose of the product. Further comment was received that the nutritional support that these products offer should be considered a critical element in differentiating them from other drinks for young children, as per the mandatory compositional requirements already agreed to for this standard.

Several respondents supporting Option 2, and therefore opposed to Option 1 and/or Option 3, cited the Procedural Manual which only requires, where appropriate or necessary, the following indications in the description of the product or products;

- the raw materials from which it is derived and any necessary references to processes of manufacture,
- types and styles of product and to type of pack, and
- additional definitions when these are required to clarify the meaning of the standard.

This was presented as support for the position that the role or purpose of the product in the diets of young children does not need to be covered in the description of the product. Others also in support of Option 2 were of the view that the text does sufficiently describe the intended role of the products in the diet and the purpose they have been manufactured for (i.e. that they are a liquid element within the diversified diet of young children).

There was minority support for Option 3 (7 CM) however several members communicated that whilst it was not their preferred option, they could support it, or a modified version of the text.

Other respondents communicated their strong opposition to a third option. It was noted that the definition has already been extensively debated and re-opening the text will further delay agreement and could lead to other options once again being proposed. Concern was also expressed that using text from a standard for complementary food was unsuitable with these respondents being of the view that this liquid product is not a complementary food, is nutritionally unnecessary, is considered a breast-milk substitute in some countries, and the definition should not create confusion between product categories.

#### Additional comments on the definition in response to CL 2021/3/OCS-NFSDU

As per [CL 2021/3/OCS-NFSDU](#) the Codex Secretariat also requested comments at Step 6 on the draft revision of Section B (specifically the scope, definition, and labelling) of the Standard for Follow-Up Formula ('Drink/Products for young children with added nutrients' or 'Drink for young children').

The Secretariat specifically requested *additional* comments on section 2.1.1 be submitted in response to the CL and noted these comments would be forwarded to the EWG for further consideration and inclusion in this Agenda Paper.

The EWG Chair has therefore undertaken an analysis and considered the *additional* comments submitted specifically on the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children' in response to the CL. The respondents to CL 2021/3/OCS-NFSDU are in Appendix III.

It is important to acknowledge that whilst the EWG considered a third proposal for the text in the definition within square brackets, this modified text was not part of the CL request for comments.

### **1.6.1 Analysis**

In response to the EWG consultation 41 respondents indicated a preferred option for the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children'. After taking into consideration the responses received to the CL this number increased to 49 respondents who provided comment on the definition (either in response to the EWG consultation and/or in response to the CL) – noting the majority of the respondents to the CL also commented on the EWG consultation paper.

It is important to note that some respondents changed their position in response to the CL from that presented in their submission to the EWG consultation. Other respondents to the CL presented proposals for a modified definition, or their response was not clear as to whether their preference was to accept or delete the text within the square brackets.

#### **1.6.1.1 Accept the text in [ ] (n=18)**

After the responses were tabulated (noting some respondents changed their preference communicated in response to the EWG consultation paper), a total of 18 (15 CM, 3 CO) respondents supported accepting the text within the square brackets. This was a slight increase from the 15 responses in support of this option in the EWG consultation paper.

#### **1.6.1.2 Delete the text in [ ] (n=17)**

Once all CL responses were considered alongside those received to the EWG consultation 17 members (1 CMO, 14 CM, 2 CO) supported deletion of the text within the square brackets contained within the definition.

#### **1.6.1.3 Modified definition (n=5)**

A total of five CMs (3 CM, 2 CO) proposed modified definitions in their response to the CL, including changes to the text already agreed to by CCFSDU. Of these, three were respondents who had supported deletion of the text in square brackets in their EWG submission, one who in the EWG



consultation supported accepting the text, and two additional members who did not provide comment on the EWG paper.

#### 1.6.1.4 Position not clear (n= 9)

From the responses received to the CL, nine (8 CM, 1 CO) of these were unclear in their position/preference for the definition. Six responses were members who had only responded to the CL and not the EWG consultation, one was a member who supported accepting the text in square brackets in their EWG response, one who had supported deletion in their EWG response, and the other respondent had indicated their preference for the modified text in the EWG paper.

### 1.7 Conclusion on definition

The EWG views were predominantly split between Options 1 and 2 presented in the consultation paper. Once responses to the CL were also considered alongside those received to the EWG consultation the outcome did not change with a relatively even split in preference for accepting and for deletion of the text contained within the square brackets of the definition. Of note, a total of 15 respondents either were not clear in their preference or presented modified text for the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children'.

The EWG Chair is of the view that based on the consolidated responses received to both the EWG consultation paper and the additional comments received in response to the CL, it is unable to put forward a recommendation on the definition for Committee agreement at CCNFSDU42.

It is therefore the recommendation of the EWG Chair that CCNFSDU42 consider the EWG comments on the definition and the responses to the CL, and focus discussions on whether the text in the square brackets within the definition be accepted or deleted, and that the Committee do not consider further options for modifying the text or an alternative definition.

#### Recommendation 1

That CCNFSDU agree to consider the EWG comments on the definition in addition to the responses to the CL and take a decision on whether the text in the square brackets within the definition be accepted (Option 1) or deleted (Option 2), and that the Committee should not consider additional options for modifying the text within the definition or an alternative definition.

##### **OPTION 1:** (accept text in the square brackets):

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children {which may contribute to the nutritional needs of young children}<sup>1</sup>

<sup>1</sup> In some countries these products are regulated as breast-milk substitutes.

##### **OPTION 2:** (delete text in the square brackets):

Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children ~~{which may contribute to the nutritional needs of young children}~~<sup>1</sup>

<sup>1</sup> In some countries these products are regulated as breast-milk substitutes.

## 2 NITROGEN TO PROTEIN CONVERSION FACTOR

### 2.1 Background

At CCNFSDU39, the Committee asked the Joint FAO/WHO Expert Meeting on Nutrition (JEMNU) for scientific advice on nitrogen to protein conversion factors (NCF) for soy-based and milk-based ingredients used in infant formula and follow-up formula (which includes formula products intended for infants, older infants and young children up to the age of 36 months).

A [systematic review](#) was first commissioned by FAO and WHO to serve as a background document for JEMNU consideration. In July 2019, an expert panel met to:

- review and interpret the evidence of a systematic review commissioned to compile and analyse the available data on nitrogen to protein conversion factors;

- determine appropriate conversion factors for soy-based and milk-based ingredients used in infant and follow-up formula; and
- make a recommendation to CCFNSDU41.

The main outcomes of [the JEMNU report](#), along with the [systematic review](#) outcomes were presented during a side event at CCFNSDU41. The Committee did not consider the outcomes in the Plenary and the 2020 EWG was subsequently charged with:

Considering the report and options provided by JEMNU in the *Nitrogen to protein conversion factors for soy-based and milk-based ingredient used in infants and follow-up formula*, and to what extent it needs to be considered for the revision of the draft standard/s for follow up formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children'.

Currently both Sections A and B of the draft revised Standard for Follow-up Formula state that '*The protein levels set in this standard are based on a nitrogen conversion factor of 6.25*'.

## 2.2 EWG consideration of NCF

The EWG consultation paper highlighted that the JEMNU report noted that the Expert Panel was '*unclear whether the recommended ranges of protein provided in the relevant Codex standards are to ensure adequate delivery of amino acids or of total protein*'. Due to this uncertainty, the Expert Panel agreed that it would be appropriate to provide two sets of conversion factors in their advice to CCFNSDU:

- one set (one for soy and one for dairy) for the sum of amino acids only, and
- one set (one for soy and one for dairy) for amino acids plus prosthetic groups.

On the basis of the results of the systematic review and the confidence in these results as assessed by the Expert Panel via the GRADE assessment process, the following conversion factors were proposed in the report:

**Option 1:** When protein is defined as being only the sum of the constituent amino acids (i.e. ensuring delivery of amino acids is the primary aim), the recommended conversion factor for dairy-based ingredients is 6.1 and for soy-based ingredients is 5.7. There was moderate certainty in the evidence underlying the conversion factor for dairy, and low certainty in the evidence underlying the conversion factor for soy.

**Option 2:** When protein is defined as being the sum of amino acids and prosthetic groups (i.e. ensuring nutrition and potential health effects of the total protein is the primary aim), the recommended conversion factor for dairy-based ingredients is 6.3 and for soy-based ingredients is 5.7. There was moderate certainty in the evidence underlying the conversion factor for dairy, and very low certainty in the evidence underlying the conversion factor for soy.

The EWG consultation paper drew attention to the Expert Panel conclusion that the selection of the most appropriate NCF ultimately depends on whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein;

*'Defining protein is particularly important because the relevance of a particular conversion factor in estimating the protein content of a food or ingredient varies, depending on whether the intention is to estimate the amount of amino acids in a food or the total protein content; that is, it depends on how protein is defined'*.

CCFNSDU did not provide a position on this when requesting scientific advice from JEMNU, nor has this fundamental question been discussed by CCFNSDU. As the EWG was tasked to look at the Expert Panel Report and the NCF only in relation to follow-up formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children', the EWG had no mandate to consider the Expert Panel recommendations and how they may apply to infant formula. However, the JEMNU Expert Panel recommendations relate to both infant and follow-up formula (which includes formula products for older infants and young children up to the age of 36 months).

## 2.3 EWG views on NCF

The consultation paper put to the EWG members four questions in relation to the JEMNU Expert Panel report and its conclusions. The responses to the questions are summarised in this section.



**QUESTION 3:**

To what extent does the JEMNU Expert Panel report need to be considered by CCNFSDU for the revision of the draft standard/s for follow-up formula for older infants and Drink/Product for young children with added nutrients, Drink for young children?

Respondents commended the work of JEMNU in general and considered it to be relevant for the revision of the draft standard(s) for follow-up formula for older infants and 'Drink/Product for young children with added nutrients', 'Drink for young children'. However, respondents acknowledged the limitations of the report and the lack of good quality data and thus the need for further work to be undertaken first before considering any change to the current NCF. While the EWG members were not directly asked for their view, many (12 CM, 1 CMO, 5 CO) expressed support for retaining 6.25 as the NCF at this point in time as per the current footnotes in Sections A and B of the draft Standard acknowledging that further work on NCF should not delay the completion of the review of the Standard for Follow-up Formula.

Some respondents (4 CM) pointed to the Expert Panel Report noting that *"the conversion factor of 6.25 currently used in the standards for infant formula and follow-up formula has not been empirically determined and agreed that its application to a wide variety of proteins is highly inappropriate. Therefore, the proposed conversion factors represent a considerable improvement over the current situation."* with one respondent raising the need to consider whether option 1 proposed in the report would be a better alternative to the current NCF while further research is undertaken.

**QUESTION 4:**

Can a NCF for follow-up formula for older infants and 'Drink/Product for young children with added nutrients', 'Drink for young children' be considered in isolation from infant formula?

The EWG was nearly unanimous (25 CM, 1 CMO, 8 CO) in that the NCF for follow-up formula for older infants and 'Drink/Product for young children with added nutrients', 'Drink for young children' cannot be considered in isolation from infant formula with only one member country expressing the opposite view. Reasons mentioned by respondents included that the products contain similar ingredients; there is overlap in the age ranges (infant formula 0-12 months and follow-on formula for older infants 6-12 months); that currently the same NCF is used for all products; that the conclusions of the JEMNU Expert Panel apply to both follow-up formula and infant formula; and that the NCF for these products should not be considered in isolation from one another unless a different NCF for a particular product for a specific age group is supported by high quality evidence.

**QUESTION 5:**

Do you agree with the Expert Panel conclusion that the selection of the most appropriate NCF (in this case for follow-up formula for older infants and 'Drink/Product for young children with added nutrients', 'Drink for young children') ultimately depends on whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein?

If yes, what should be the process for addressing this question? How (and by whom) should this work be undertaken?

There was majority agreement (20 CM, 1 CMO, 7 CO) that the selection of the most appropriate NCF depends on whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein and that a decision on this needs to be taken first. While the consultation paper did not specifically ask respondents to state their view on what the primary aim of determining protein content is, 12 respondents went on to say that it should be total protein. The justification provided by many was that the protein reference for breast-milk substitutes for infants is breastmilk; the Kjeldahl method currently used determines total protein based on measurement of total nitrogen content; and that the Codex Standards for formula products for infants specify both the required range for protein in the product and separately requirements for amino acids. One respondent stated that in their view the primary aim of determining protein content is the delivery of amino acids. Some (6 CM, 2 CO) additionally commented that in setting a NCF the diversity of protein sources needs to be considered as well as the variable composition of protein ingredients.

The responses to what should be the process for addressing the above question and how (and by whom) should this work be undertaken were mixed. Several respondents considered that this would be for JEMNU or other experts in the field, and others suggested a discussion at CCNFSDU but for this

process to be independent of the work on the review of the Standard for Follow-up Formula. Some respondents saw no benefit to be achieved from modifying the NCF for formula products for infants and young children as the protein content and amino acid requirements in the relevant Codex Standards already ensure an adequate protein quantity and quality in the products.

#### **QUESTION 6:**

What are the implications of a change in the NCF (if supported) in the standard/s for follow-up formula from the status quo of 6.25?

The majority of the respondents to the question (16 CM, 4 CO) mentioned that a change to the NCF would require re-opening the minimum and maximum protein levels within the draft revised Standard and the subsequent need to revisit the other macronutrient levels in order to meet the energy requirement should there be any changes to the protein requirements. This was highlighted as an issue for consideration in the EWG consultation paper. A number of respondents (7 CM, 1 CMO, 1 CO) also acknowledged that re-opening the compositional requirements that are already held at step 7 would result in delays in finalising the review of the Standard for Follow-up Formula. Many (9 CM, 1 CMO, 1 CO) were of the view that a change to the NCF in the Standard for Follow-up Formula will also result in a need for consequential changes to the Infant Formula Standard and will also have a large impact on other Codex standards and guidelines.

Other possible implications mentioned by respondents included the following:

- The new NCF's proposed by the Expert Panel do not cover all permissible forms of protein and would result in a regulatory gap as there would be no default NCF to use
- There may be a need to reconsider analytical methods as the Kjeldahl measures total protein which may no longer be appropriate
- New protein and amino acid limits in Infant and Follow-up Formula Standard(s) would trigger revision of related national regulations in member countries
- The potential for different NCFs being applied in different markets resulting in the need for multiple product labels for the same product
- The potential for unfair trade advantages for other plant based proteins should NCF be changed for soy without specific NCFs for other plant based proteins
- Noting the low grade of evidence, concern that the use of an inaccurately low NCF for soy-based ingredients would create a potential for exceeding the recommended daily protein intake for infants and young children
- The need for label changes and product reformulation of products on the market that already comply with the revised compositional requirements held at step 7
- Possible need for communication to consumers regarding changes in protein values on the product label

Despite the identified implications of changing the NCF a number of respondents commented that Codex should continue the work on NCFs as they should have a strong scientific basis. Comment was also made that the work on NCF is not relevant as follow-up formula for older infants and 'Drink/product for young children with added nutrients', 'Drink for young children' are not necessary.

#### **2.4 Conclusion on NCF**

The EWG was nearly unanimous in its view that the NCF for follow-up formula for older infants and 'Drink/Product for young children with added nutrients', 'Drink for young children' cannot be considered in isolation from infant formula. The EWG majority view was also that prior to considering a change to the NCF a decision needs to be taken whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein before considering the most appropriate NCF.

As the mandate of the work on the review of the Standard for Follow-up Formula does not extend to infant formula, and noting the EWG support that the work on the review of the Standard for Follow-up Formula should not be delayed by the consideration of the primary aim of determining protein content, the Chair recommends that the NCF of 6.25 is retained in the standard(s) and that NCF is not considered further as part of the work on the review of the Standard for Follow-up Formula.

**Recommendation 2**

That CCNFSDU agree that the NCF of 6.25 is retained in the standard(s) for Follow-up Formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children'.

## APPENDIX II

## LIST OF 2020 EWG PARTICIPANTS

**Codex Members & Codex Member Organisation**

- |                        |                 |                                  |
|------------------------|-----------------|----------------------------------|
| 1. Argentina           | 17. India       | 33. Peru                         |
| 2. Australia           | 18. Indonesia   | 34. The Philippines              |
| 3. Austria             | 19. Iran        | 35. Poland                       |
| 4. Brazil              | 20. Ireland     | 36. Republic of Korea            |
| 5. Burkina Faso        | 21. Japan       | 37. Russian Federation           |
| 6. Cambodia            | 22. Kuwait      | 38. Saudi Arabia                 |
| 7. Canada              | 23. Malaysia    | 39. Senegal                      |
| 8. Chile               | 24. Mali        | 40. Singapore                    |
| 9. China               | 25. Mexico      | 41. South Africa                 |
| 10. Colombia           | 26. Morocco     | 42. Switzerland                  |
| 11. Costa Rica         | 27. Nepal       | 43. Thailand                     |
| 12. Egypt              | 28. New Zealand | 44. Uganda                       |
| 13. The European Union | 29. Niger       | 45. United Kingdom               |
| 14. France             | 30. Nigeria     | 46. The United States of America |
| 15. Germany            | 31. Norway      | 47. Uruguay                      |
| 16. Guatemala          | 32. Panama      | 48. Vietnam                      |

**Codex Observers**

1. American Oil Chemists' Society (AOCS)
2. Comité Européen des fabricants de sucre (CEFS)
3. European Natural Soyfoods Manufacturers Association (ENSA)
4. European Network of Childbirth Associations (ENCA)
5. European Vegetable Protein Association (EUVEPRO)
6. Federation of European Specialty Food Ingredients Industries (EUSFI)
7. Helen Keller International (HKI)
8. Institute of Food Technologies (IFT)
9. International Baby Food Action Network (IBFAN)
10. International Council of Grocery Manufacturers Associations (ICGMA)
11. International Dairy Federation (IDF)
12. International Lactation Consultant Association (ILCA)
13. International Special Dietary Foods Industries (ISDI)
14. Specialised Nutrition Europe (SNE)
15. The United Nations Children's Fund (UNICEF)
16. World Public Health Nutrition Association (WPHNA)

**APPENDIX III****LIST OF RESPONDENTS TO CL 2021/3/OCS-NFSDU<sup>2</sup>**

Respondents who provided comment on section 2.1.1 definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children'.

**Codex Members**

1. Brazil
2. Chile
3. Colombia
4. Costa Rica
5. Cuba
6. Ecuador
7. Egypt
8. Guatemala
9. Jamaica
10. Indonesia
11. Malaysia
12. Mexico
13. New Zealand
14. Nigeria
15. Panama
16. Paraguay
17. Peru
18. The Philippines
19. Syrian Arab Republic
20. Thailand
21. Uganda
22. United Arab Emirates
23. United Kingdom
24. The United States of America
25. Venezuela
26. Zambia

**Codex Observers**

1. European Federation of the Associations of Dietitians (EFAD)
2. European Network of Childbirth Associations (ENCA)
3. International Baby Food Action Network (IBFAN)
4. International Special Dietary Foods Industries (ISDI)

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<sup>2</sup> Comments are available [here](#) and also in CX/NFSDU 21/42/5 Add.1