## CODEX ALIMENTARIUS COMMISSION





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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 21/42/5 Add.2

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

## **Forty-second Session**

## Virtual

19 - 25 November and 1 December 2021

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

DRAFT PRODUCT DEFINITION OF DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN, AND NITROGEN TO PROTEIN CONVERSION FACTORS: EWG REPORT

## Comments in reply to CL 2021/54/OCS-NFSDU

Comments of Brazil, Burkina Faso, Canada, Chile, Colombia, Costa Rica, Cuba, Egypt, European Union, Ghana, Guatemala, India, Indonesia, Iraq, Japan, Kenya, Kuwait, Malaysia, Mali, Morocco, Nepal, New Zealand, Niger, Nigeria, Norway, Paraguay, Peru, Philippines, Republic of Korea, Saudi Arabia, Senegal, Switzerland, Thailand, United Kingdom, United States of America, Uruguay, Consumers International, ENCA, ENSA, HKI, IBFAN, EUVEPRO, IDF, IACFO, ISDI, UNICEF, WFPHA, WPHNA

## **Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/54/OCS-NFSDU issued in August 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

## Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

COMMENTS	MEMBER / OBSERVER
DRAFT PRODUCT DEFINITION OF DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN	
Recommendation 1 (Option 1 or 2)	
Brazil reiterates its position expressed in the eWG and sent in response to CL 2019/113/OCS-NFSDU and CL 2021/3/OCS-NFSDU, as copied bellow:	Brazil
Brazil prefers option 2. We are of the opinion that the purpose and the target population of the product are already covered in the text: "a product manufactured for use as a liquid part of the diversified diet of young children".	
Brazil considers that the text in square brackets should be deleted since other products or family foods traditionally used as part of the diversified diet of young children may also contribute to the nutritional needs of young children. Thus, the phrase in square brackets could give a false concept of superiority of this product in relation to other foods used in the diet of this age group.	
For consistency, Brazil suggests that the word "product" also applies to the name 'Drink for young children'. Thus, the names would read: 'Drink/product for young children with added nutrients' or 'Drink/product for young children' throughout the text of the standard where the product name is mentioned.	
Burkina Faso supports the deletion of the text in square brackets in option 2.	Burkina Faso
Comments both technical and editorial: Canada agrees with the definition in option 1 and supports retaining the text in square brackets to help differentiate these types of products from other beverages consumed by young children. Option 1 adequately describes the purpose of the product. Excluding the text in square brackets in option 2 makes the definition too broad and does not allow the consumer to differentiate these products from other beverages for young children.	Canada
In general, we agree with the document on an overall level, and we support its continuation.	Chile
OPTION 2: We do not agree with keeping the phrase "that can contribute to the nutritional needs of young children" in the text. However, we believe that it is important to distinguish this product from other products used as drinks by this age group, and propose the following phrase, replacing the one currently in square brackets: "which has been produced according to the compositional requirements laid down in this standard".	
At the meetings held in the subcommittee there is agreement on option 1, given that it will primarily contribute to improving the actions of inspection, oversight and control that may be carried out.	Colombia
Costa Rica firstly supports option 2, given that the inclusion of the words "that can contribute to the nutritional needs of young children" is not included in the PRODUCT DEFINITION, section 2.1.1, and could describe its role even though it does not have that role. This wording is interpreted as though the product could help compensate nutritional deficiencies during the transition of young children to a family diet, implying a statement about the product that might be false. We believe it goes against the Procedural Manual's provisions on definitions, and confuses those products and their roles with the roles defined for other products. It cannot be assumed and asserted that those products can contribute to the nutritional needs of young children, therefore, Costa Rica could not support option 1.	Costa Rica
Cuba is grateful for the opportunity to comment on circular letter CL 2021/54/OCS-NFSDU, in the sense that we agree with advancing the proposed draft to step 5, and we are of the view that the definition should be: "product with added nutrients for young children", as it is simpler for the general public to understand. We also agree with the term in square brackets [that can contribute to the nutritional needs of young children] as it is a general statement and is not misleading.	Cuba

Egypt supports Option 2, to delete text in the square brackets (which may contribute to the nutritional needs of young children). The text will be as follow:  - Drink /product for young children with added nutrients means a product manufactured for use as a liquid part of the diversified diet of young children 1.  Egypt in a view that the text does sufficiently describe the product (Drink/product for young children with added nutrients) as well as the intended role of the products in the diet and the purpose they have been manufactured for (Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children). The EU supports the Chairs' recommendation that the Committee should not consider additional options for modifying the text within the definition or an alternative definition. As to the proposed options, the EU supports option 2, i.e. the deletion of the text in square brackets "(which may contribute to the nutritional needs of young children)" As the EU already mentioned during the previous consultations, the EU supports option 2, i.e. the deletion of the text in square brackets "(which may contribute to the nutritional needs of young children)" when compared to other foods that may be included in their normal diet.  The EU is therefore of the view that the proposed definition (under option 2) sufficiently describes the intended role of the products in the diet of the target group and the purpose they have been manufactured for (i.e. that they are liquid elements in the diversified diet of young children and works to adequately describe the purpose of the product.  We are of the opinion that option 1 should be accepted. We believe it is essential for the sentence (that can contribute to the nutritional needs of young children) to be retained in CCNFSDU42 in the product definition, section 2.1.1, regarding the role of the product. We believe the purpose of the product and product can contribute to or perform a role in the treatment of the nutritional nee		
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the following comments:	Yes agree	
- Recommendation 1		Indonesia
	- Recommendation 1	

Indonesia supports Option 1 to accept text in the square brackets.	
Agree with OPTION 2: (delete text in the square brackets).	Iraq
Kenya supports adoption of option 2 (without the statements) along with the footnote  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.  We find text under discussion, 'which may contribute to the nutritional needs of young children', as superfluous given that it implies that the products may have nutritional properties or not yet the compositional requirements provide as some essential requirements a number of nutrient. This statement therefore does not any additional necessary information. We also note the guidance of description by the procedural manual does not require such statements.	Kenya
We agree on OPTION 2 delete text in the square brackets.	Kuwait
In addition to Keep "Drink for young children" only! delete "with added nutrients" it is a misleading claim that may give the impression that it is a necessary nutritional requirement for young children while the use of follow-up products has been declared "not necessary" by the WHO. This will lead to conflicting messages delivered by health providers to families.	
Also drinks for young children must carry the warnings regarding possible contamination for products in powdered form according to the (WHO/FAO (2007) guidelines, and WHA resolutions 58.32 (2005) and 61.20 (2008). Also, the Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008).	
Drinks for young children function as breastmilk substitutes that should be in the scope of the International Code and subsequent relevant WHA Resolutions articles.	
Malaysia supports Option 1 to retain the sentence in square brackets [which may contribute to the nutritional needs of young children]1 in the product definition, section 2.1.1 concerning that milk is still be a required and wholesome food for growing children during transition to a family-based diet. Almost all dietary guidelines in the world recommend the consumption of milk by children and all age groups and therefore, nutritious milk should be made available. A clear definition is important to ensure the correct application of the Standard by regulators and food business operators.	Malaysia
Malaysia would like to reiterate our previous comments response to CL in Mach 2020 to align the text used for consistency by adding the word "product" to "Drink/product for young children"	
The rationale for this proposal are as follows:	
<ul> <li>According to CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CODEX STAN 1-1985) the name should be specific and not generic.</li> </ul>	
"Drink" is not an appropriate denomination for certain countries (meaning it is a liquid to be given to relieve thirst).	
<ul> <li>It is normally a requirement in Codex texts that the name of the product reflects the true nature of the food.</li> </ul>	
Mali has noted the fact that no discussions will take place on the supplementary options for modifying the text that is under discussion and that the meeting will focus solely on the question of determining whether the text in square brackets should or should not be included.	Mali
We remain firmly convinced, as we have always been, that the text in square brackets is not necessary, does not fall under the mandate of the Codex and must be deleted (option 2).	

1. The purpose of the definition is to respond to the requirements of the Procedural Manual of the Codex, which states the following on page 57 relating to the description: "This section must contain a definition of the product or products with an indication, if required, of the raw materials they are made of and any necessary references to the production processes. It can also include references to the type and style of product and the type of packaging. It can also contain additional definitions if these are needed to clarify the meaning of the standard."

According to Mali's understanding of the text above, the essential elements of the definition are the following four items, where this is appropriate/necessary:

- 1. The raw materials it is made of.
- 2. The production process.
- 3. The type and style of product and the type of packaging.
- 4. Additional definitions if these are needed to clarify the meaning of the standard
  - No. 1. The raw materials are not currently covered by the description, but they are referred to elsewhere in the standard and are therefore not required in the definition.
  - No. 2. The production process is covered by the text in section 2.1.2 and is therefore not needed in the definition.
  - No. 3. The types and styles can be considered to be covered by part of section 2.1.1, namely "...to be used as a liquid part of...", and by part of section 2.1.2, namely "...packaged in such a way as to avoid deterioration or contamination...". Therefore, it is not necessary to mention them in the definition.
  - No. 4. We believe that paragraph 2.2.1 covers this point by providing a definition of "young children". Therefore, it is not necessary to include this in the definition.

We do not think that the role or purpose of the product in the diet of young children is a necessary part of the description, in accordance with the Procedural Manual. In addition, definitions must be clear, accurate and unambiguous and must not include any statements about what the product can and cannot do, depending on the circumstances, unless the circumstances are clearly specified. The text in square brackets is superfluous and must be deleted.

- 2. The text in square brackets must be deleted, because the World Health Assembly (WHA), the world's highest level policy-making body in the field of health, has agreed that these products are not necessary. By including the text in square brackets, the Codex gives the impression that these products actually have a role to play in the diet of young children, which is not the case. They are undoubtedly useless.
- 3. It is essential to note that making it mandatory to include certain nutrients or to specify the inclusion or exclusion of certain ingredients or to specify the levels in the composition of these products is a normal part of the process of establishing the standards of the Codex and therefore does not need to be highlighted in the definition and must not indicate that the product offers specific advantages. This precedent has been established in the following definition of the follow-up formula for older infants: "designates a product manufactured for use as a substitute for breast milk, as a liquid element of a diet for older infants when complementary feeding is introduced and progressively diversified". There are many mandatory nutrients and specific fixed levels in the composition of this product, but is rightly not highlighted in the definition. Given that the drink/product for young children in question is a similar product but intended for the next age category and that this concerns part A and part B of the same standard, the definitions must be in line with one another and consistent. Therefore, they must not include the text in square brackets and must read as follows: "designates a product manufactured for use as a liquid element of diversified feeding for young children."

Mali

4. The fact that adding certain nutrients is mandatory and that the specific levels are fixed for certain nutrients does not mean that these products can be considered to be necessary on a global scale. The member states have agreed that these products are useless, regardless of their composition. The advantages of these products compared with continued breastfeeding, which is recommended for this age group, have not been demonstrated, but there is extensive evidence of the advantages of continued breastfeeding. It has also been proved that these products replace breast milk in the diet, which leads to a net reduction in the recommended nutritional intake from breast milk. This is contrary to the proposed text. In addition, it is important to note that point 3.2 of the standard allows optional ingredients to be added. This could change the general profile of the product, in particular because the evidence about a series of ingredients and the ultra-processing of the foods gives rise to a number of concerns. The text in square brackets could prove to be incorrect and therefore must be deleted.

- 5. It is important to note that any contribution made by these products to the diets of young children is not the same in every country and is therefore deceptive. As the Committee acknowledges, in certain situations these products can make a positive nutritional contribution to the diet. However, in many cases they are not necessary and can have a negative impact because they interfere with continued breastfeeding, but also because of the concerns about certain ingredients and their ultra-processing. The proportion of children liable to be affected positively or negatively will vary significantly from one member state to another and even though the statement may be accurate for some, it will be incorrect or deceptive for others. Therefore, it is inappropriate for a statement that does not apply equally to all the member states to be included in the definition of a Codex document. It must be deleted. If it is retained, it must read as follows: "...may or may not contribute...". In addition, the inclusion of the text in square brackets does not fall under the mandate of the Codex. The Codex should not establish a universal principle concerning the nutritional requirements of young children. It is the responsibility of the member states to determine which foods/drinks contribute to the nutritional requirements of their specific population/groups of the sub-population.
- 6. Mali and many other country delegations and observers have firmly stated that this definition should include the fact that these products act as substitutes for breast milk and are defined as such in many countries. This has not been accepted because it has been made clear that this was not the case in other countries. In order to reach a consensus, the decision was made that "the Codex will remain silent on the question of whether or not the product should be described as a substitute for breast milk". We think, therefore, that if we apply the same principle in order to reach a consensus, this definition should remain silent on the question of whether this product can or cannot contribute to the nutritional requirements of young children.

The text should therefore read as follows:

Drink/product for young children with added nutrients or drink/product for young children designated as a product manufactured for use as the liquid element of a diversified diet for young children.<sup>1</sup>

#### Note:

Mali believes that if the Committee decides to keep the text in square brackets, it will be essential to carry out a consultation/examination and to hold additional discussions on this text, because as it is currently drafted, it is deceptive and undermines the previous discussions and consensuses reached by the Committee on similar questions (for example, the use of the term "formulated").

Morocco support "Option 1"

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]1

Nepal strongly opts for OPTION 2, with the deletion of the text in square brackets.

Nepal

<sup>&</sup>lt;sup>1</sup> In some countries, these products are regulated as substitutes for breast milk.

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Nepal always believes that these products are unnecessary as our regulation and programs promote breastfeeding and discourage breastmilk substitutes. The amendment in Nepal's current legislation has covered these products as breast-milk substitutes and prohibits any nutrition and health claims by these products. However, the current text signifies that these products are of nutritional significance and are necessary.	
Nepal believes that the text within the square brackets may further confuse people and therefore encourage these unnecessary products which are expensive compared to the equivalent amount of plain milk and has a concern of added sugar contributing to the added sugar in the diet of the young children which may lead them to prefer to sweet drinks over plain milk. Nepal believes on other evidence-based and low-cost public health measures to supplement nutrients which are lacking or are present in insufficient quantities in the local diet.	
Therefore, Nepal strongly proposes to delete the text in the []. Thus, the statement should read as:	
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 children1 1 In some countries these products are regulated as breast-milk substitutes.	
Recommendation 1:	New Zealand
New Zealand supports Option 1, that is to accept the text in square brackets within the definition for Drink/product for young children with added nutrients or Drink for young children.  The definition would therefore read; 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]1  In some countries these products are regulated as breast-milk substitutes.	
New Zealand supports Option 1 as it assists in differentiating these products from other drinks for this age group by stating that they contribute to the nutritional needs of young children. New Zealand notes the guiding principles for the mandatory (core) composition of product for young children including Principle 1: Contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate and believes that by retaining the text in square brackets it helps define these products as per the principles that guided the mandatory composition and which were agreed to by the Committee.	
In accordance with the regulations in our country concerning the commercialisation of breast milk substitutes and other preparations for young children, we support option 2. This is also consistent with the recommendations of the World Health Assembly (WHA) which has agreed that these products are not necessary. As a result, the text in square brackets is not necessary, does not fall under the mandate of the Codex and must be deleted. Niger has supported this position since the last meeting of the CCNFSDU held in Germany in November 2019. Therefore, the following text should be kept, in accordance with the majority view that seemed to emerge from the meeting of the CCNFSDU in 2019: Drink/product for young children with added nutrients or drink for young children designated as a product intended for use as the liquid element of a diversified diet for young children.	Niger
In keeping with our previous submission on the definition, Nigeria reiterates her opinion that the text in square brackets [which may contribute to the nutritional needs of young children] should be deleted. Nigeria, therefore, is in favour of OPTION 2 which is to delete the text in square brackets and for the definition to read:	Nigeria
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. <sup>1</sup> 1 In some countries these products are regulated as breast-milk substitutes.	
Rationale: Nigeria notes that there is a clear statement from the World Health Assembly (WHA), the decision-making body of the World Health Organization (WHO), that these products are not necessary. They are not necessary products in the diets of young children, and this is	

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regardless of their composition. The text in square brackets suggests and implies that the products are somewhat necessary to meet the nutritional needs of young children, which they are not, and the statement should therefore not form part of the definition of the product.	
Nigeria is of the opinion that it is not appropriate, and would in fact be misleading, to include in the definition, a statement that is not universally applicable across all Member States. The text in square brackets should be deleted and if for any reason the Committee sees any value in retaining the text, it should be removed from the definition and included as a footnote which should read "these products may or may not contribute to the nutritional needs of young children". A precedent for this has already been set by the Committee with the inclusion of footnote1 to the definition in order to reach consensus. At the time, it was decided (despite strong opposing views from Nigeria and many country delegations) not to include in the definition that these products function as breastmilk substitutes even though they were defined as such in many countries because this was not the case in some countries. Relevant section of REP20/NFSDU is in paragraph 60:	
"the Committee reached agreement on a revised definition that followed the guidance of the EWG 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 the fact that these products are regulated as breastmilk substitutes in some countries." (para 60 REP20/NFSDU).	
In conclusion, Nigeria is of the opinion that the text in square brackets should be deleted from the definition. However, if the Committee reaches a stage during discussions where it becomes expedient in order to reach consensus, the same principle should apply. That is, delete the text in square brackets from the definition and consider its inclusion as amended as a footnote to the definition.	
Norway supports the recommendation given by the Chair, that the Committee should not consider additional options for modifying the text within the definition or an alternative definition. As to the proposed options, Norway supports option 2, that the text in square brackets should be deleted: "[which may contribute to the nutritional needs of young children]". The rationale is that these products are unnecessary, as clearly stated by The World Health Assembly (WHA), the world's highest health policy setting body. Also, the European Food Safety Authority (EFSA) noted in their scientific advice on young child formulae from 2013, that these products have "no unique role" and "cannot be considered as a necessity to satisfy the nutritional requirements of young children", when compared to other foods that may be included in their normal diet. Including the text in square brackets would give the impression that these products play a role in the diets of young children, which is not correct.	Norway
Paraguay is grateful for the opportunity to reply to this Circular Letter. We also concur with the proposal of the Nitrogen-to-Protein Conversion Factors; therefore, we support the document's advancement to the next step.	Paraguay
"Drink/product for young children with added nutrients or drink for young children means any product manufactured for use as a liquid part of the diversified diet of young children [that can contribute to the nutritional needs of young children].	
We think it advisable to delete the wording in square brackets, as it is ambiguous.	
Peru thanks the Secretariat of the Codex Alimentarius Commission for sending Circular Letter CL 2021/54/OCS-NFSDU Request for observations on the draft product definition of drink/product for young children with added nutrients or drink for young children; and nitrogento-protein conversion factors: report by the Electronic Working Group (eWG)	Peru
Peru has analysed the document and has the following comments:	
<ol> <li>Peru believes the text in square brackets [that can contribute to the nutritional needs of young children] in the product definition should be retained.</li> </ol>	
Peru believes the nitrogen-to-protein conversion factor of 6.25 should be used in the Standard or Standards for Follow-Up Formula for Older Infants, and "drink/product for young children with added nutrients" or "drink for young children".	

The Philippines expresses its support to the rest of the texts of Section B of the Proposed Draft Revised Standard for Follow Up Formula with **Philippines** some comments in conformance with the previous Philippine Positions on the review of the Revised Standard for Follow-Up Formula (CXS 156-1987) The Philippines prefers Option 2 (Delete text in square brackets):. Drink/product for young children with added nutrients or Drink for young children manufactured for use as a liquid part of the diversified diet of young children. 1 In some countries these products are regulated as breast-milk substitutes. We believe that the bracketed texts "which may contribute to the nutritional needs of young children" should be deleted since it is redundant as contribution to nutritional needs is already covered by the additional phrase "with added nutrients. We are of the opinion that these products are not essential to the diet of the child when a proper and balanced diet is being consumed. Further the text in square brackets should be deleted as the World Health Assembly (WHA), the world's highest health policy setting body, has agreed that these products are unnecessary. We believe that the purpose of this product is covered by the phrase "manufactured for use as a liquid part of the diversified diet of young children. Furthermore, contribution to nutritional needs of intended age group does not need to be highlighted in the definition, nor does it mean that the product offers specific benefits. This precedent is set with the definition of 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." There are many mandated nutrients and specific levels set in the composition of this product, but this is correctly not highlighted in the definition. As the drink/product for young children under discussion is a similar product but for the next age category and to be Part A and Part B of the same standard, the definitions should be aligned and consistent and should therefore not include the text in square brackets. Lastly, the bracketed text may lead to inappropriate promotion of these products as having a health benefit, which would undermine breastfeeding and run counter to the WHO guidance that breast milk is the most appropriate liquid part of a progressively diversified diet once complementary feeding has begun. For consistency, we request that for section 9.1.2, NAME OF THE PRODUCT Drink/product for young children with added nutrients", or "Drink for young children" the word "product" also applies to "drink for young children". The product names would then read: "Drink/Product for Young Children with Added Nutrients" or "Drink/Product for Young Children. This recommendation is in conformity with the CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CODEX STAN 1-1985) and in compliance with the Philippine Labeling Guidelines (Administrative Order 2014-0030). The product name should be specific and not generic and it should reflect the true nature of the product. "Drink" alone may not be an appropriate denomination as it may connote that the product is liquid in form which may not always be the case for certain countries such as the Philippines. Consistent with previous Philippine Positions, we reiterate the inclusion of relevant recommendations made in the International Code of Marketing Breast-milk Substitute (1981) and the Global Strategy of Infant and Young Child Feeding, WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions in Sections A and B of the Proposed Draft Revised Standard for Follow Up Formula and Product with Added Nutrients/Product for Young Children to protect the practice of breastfeeding under Scope or in the Preamble. This issue was raised in the 43rd Session of the Codex Alimentarius Commission and no less than the Chair of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) committed to open the discussion on addition of such resolutions in the coming CCNFSDU Session. We are of the opinion that the Committee should take into account including such resolutions as these have been supported by Member States to provide guidance to countries in this context. Republic of Korea supports option 1 for the definition of CXS 156-1987. We view that Option 1 includes the purpose of the product and the Republic of Korea description of the intended role of the product in the diet. Retaining the text in the square brackets should help to differentiate the products from other beverages for young children and work well to describe the purpose of the product. Saudi Arabia preferred Option 2, which means deleting the text in the square brackets,

Saudi Arabia

## For the following rationales:

1- EFSA has found no scientific evidence, or sufficient evidence, to support the inclusion of many of the ingredients commonly used in formulas and promoted as having a health benefit. The EFSA Scientific Opinion on the essential composition of infant and follow-on formulae, EFSA, has warned that the unnecessary addition of nutrients can be a burden to a young child metabolism.

2- WHO recommends exclusive breastfeeding for the first six months of an infant's life. Thereafter, local, nutritious foods should be introduced, while breastfeeding continues for up to two years or beyond. Follow-up formula is therefore unnecessary. In addition, follow-up formula, due to its content, is not a suitable substitute for breast milk.

Senegal has noted the fact that no discussions will take place on the supplementary options for modifying the text in question and that the meeting will focus solely on the question of determining whether the text in square brackets should or should not be included.

We are convinced that the text in square brackets is not necessary and that it must therefore be deleted (option 2).

#### Explanation:

Senegal does not believe that the role or purpose of the product in the diet of young children is a necessary part of the description, in accordance with the Procedural Manual. In addition, definitions must be clear, accurate and unambiguous and must not include any statements about what the product can and cannot do, depending on the circumstances.

The text in square brackets must be deleted because, according to the World Health Assembly (WHA), these products are not necessary. By including the text in square brackets, the Codex gives the impression that these products have a role to play in the diet of young children, which is not the case.

The text should therefore read as follows:

Drink/product for young children with added nutrients or drink for young children designated as a product manufactured for use as the liquid element of a diversified diet for young children.<sup>1</sup>

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

Therefore, Senegal believes that if the Committee decides to keep the text in square brackets, it will be essential to carry out a consultation/examination and to hold additional discussions on this text, because as it is currently drafted, it is deceptive and undermines the previous discussions and consensuses reached by the Committee on similar questions.

**OPTION 1:** Senegal does not believe that the role or purpose of the product in the diet of young children is a necessary part of the description, in accordance with the Procedural Manual. In addition, definitions must be clear, accurate and unambiguous and must not include any statements about what the product can and cannot do, depending on the circumstances.

The text in square brackets must be deleted because according to the World Health Assembly (WHA) these products are not necessary. By including the text in square brackets, the Codex gives the impression that these products have a role to play in the diet of young children, which is not the case.

The text should therefore read as follows:

Drink/product for young children with added nutrients or drink/product for young children designated as a product manufactured for use as the liquid element of a diversified diet for young children.<sup>1</sup>

Senegal

<sup>&</sup>lt;sup>1</sup> In some countries, these products are regulated as substitutes for breast milk.

Therefore, Senegal believes that if the Committee decides to keep the text in square brackets, it will be essential to carry out a	
consultation/examination and to hold additional discussions on this text, because as it is currently drafted, it is deceptive and undermines the previous discussions and consensuses reached by the Committee on similar questions.	
As to the proposed options, Switzerland supports option 2, i.e. the deletion of the text in square brackets " [which may contribute to the nutritional needs of young children]".	Switzerland
Switzerland considers that these products have "no unique role" and "cannot be considered as a necessity to satisfy the nutritional requirements of young children" when compared to other foods that may be included in their normal diet.	
Switzerland is therefore of the view that the proposed definition (under option 2) sufficiently describes the intended role of the products in the diet of the target group and the purpose they have been manufactured for (i.e. that they are liquid elements in the diversified diet of young children).	
We agree with Option 1 that accepts text in the square brackets, so the definition should read as follows:	Thailand
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 children1	
1 In some countries these products are regulated as breast-milk substitutes.	
The UK does not consider these products necessary and any definition should not idealise these products or imply that they are necessary. Option 2 is our preferred option as it does not idealise these products.	United Kingdom
Uruguay does not agree with accepting the text between square brackets. We believe OPTION 2 (deleting the text between square brackets) is appropriate.	Uruguay
We chose this option as it sufficiently describes the intended role of the products in the child's diet and the purpose for which they have been manufactured, without needing to include further detail.	
Moreover, the definition should neither idealise nor promote these products in any way, nor imply they are necessary for the proper growth and development of young children, and we think the inclusion of the text between square brackets could prompt that.	
In agreement with this option 2 for the reasons set out above.	
The United States would prefer Option 1 but can accept Option 2 as we feel the text in square brackets is not essential for a definition that expresses the basic nature of the product produced according to the standard. The addition of mandatory nutrients has a sound scientific basis as many young children do not get adequate amounts of those nutrients and these beverages may contribute to the nutritional needs of young children. Thus, the text in square brackets provides important context to the definition.	USA
However, the United States does not believe the current definition is sufficiently descriptive to characterize the basic nature of the product. The drink/product for young children can be defined by the two characterizing mandatory ingredients which are protein and nutrients.	
The United States offers the following clarification edits to the definition in order to sufficiently characterize the basic nature of the product:	
"[INSERT: A protein-based] drink/product for young children with added nutrients or a [INSERT: protein-based] drink [INSERT: /product] for young children manufactured for use as a liquid part of the diversified diet of young children."	

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The United States notes that product definitions in Codex texts/standards are an important part of providing clarity and transparency to the basic nature of the product being produced according to the standard. Product definitions do not appear on labels or the labelling of the product.	
In the United States, regulations governing the establishment of food standards require a product definition that is sufficiently descriptive so that the user of the standard understands the nature of the product produced in accordance with the standard. Clear definitions are critical to assuring that regulatory authorities are able to determine compliance with the requirements of the standard. Terms such as 'protein' and 'nutrients' are necessary for defining the product of this standard as they are characterizing ingredients of the product and are factual statements, not 'claims'.	
The United States' interpretation of the Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) provides guidance that is equally appropriate to apply to definitions sections of Codex standards.	
Finally, we note that there are provisions in the Codex Procedural Manual governing the Format for Codex Commodity Standards (see pp. 55-60 in the 27th Ed). Since this is a commodity standard, and the EWG report refers to these provisions in Sections 1.3-1.4, the United States believes that this may be a helpful reference for putting our comments into context.	
Here is a relevant excerpt from the Codex Procedural Manual (page 56 of the 27th Ed):	
Description	
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.	
The text in square brackets should be deleted as the existing science-based evidence does not provide any indication that these products are either useful or necessary for children. Indeed, the norm setting body of the WHO, the World Health Assembly (WHA) has confirmed that these products are unnecessary. If the bracketed text is included in the codex text it would not be aligned with WHO recommendations and gives the false impression that these products are a necessary part of young children's diets. The bracketed text also would mask the many risks that these, often heavily processed, products pose for children at this crucial stage of their development. This bracketed text would also add to the impression already giving by existing marketing and cross-promotion that these products are necessary and useful for young children.	Consumers International
Option 2	ENCA
Against Option 1	
Helen Keller International has taken cognisance of the note that no discussion will be entered into regarding additional options for modifying the text under discussion and that the meeting will focus only on if the text in square brackets should or should not be included.	НКІ
It always has been and remains our firm opinion that the text in square brackets is not necessary and not within Codex's mandate and should be deleted.	
Justification:	
1. The purpose of the definition is to fulfil the requirements of the Codex Procedural Manual that on p57 related to description that states: "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."	

The critical elements that should form part of the definition are, based on HKI's understanding of the above text, where appropriate/necessary, 4 things:

- 1. The raw materials from which it is derived.
- 2. Process of manufacture.
- 3. Types and styles of product and type of pack.
- 4. Additional definitions when these are required to clarify the meaning of the standard.

It is HKI's view that, considering the above:

- No 1. related to raw materials is currently not covered in the description but is addressed elsewhere in the standard so is not required in the definition.
- No 2. Process of manufacture is covered in the text of 2.1.2 so not required in the definition.
- No 3. Types and styles could be considered covered in part of 2.1.1 namely "...for use as the liquid part of the..." and part of 2.1.2 namely "...so packaged as to prevent spoilage or contamination..."It therefore does not need to be covered in the definition.
- No 4. We believe 2.2.1 covers this by providing a definition for 'young children'. It therefore does not need to be included in the definition.

We therefore do not believe that the role or purpose of the product in the diets of young children is necessary in the description as per the procedural manual. Further, a definition should be clear, precise and unambiguous, and does not benefit from a statement about what the product may or may not do, depending on the circumstances – without those circumstances being clearly articulated. The text is square brackets is extraneous and should be deleted.

- 2. The text in square brackets should be deleted as the World Health Assembly (WHA), the world's highest health policy setting body, has agreed that these products are unnecessary. By including the text in square brackets, the impression is given by Codex that these products do in fact have a role to play in the diets of young children, which is not the case they are unequivocally unnecessary.
- 3. It is critical to note that mandating certain nutrients to be included or specifying the inclusion or exclusion of certain ingredients or specifying levels in the composition of these products, is a normal part of the Codex standard setting process and therefore does not need to be highlighted in the definition, nor does it mean that the product offers specific benefits. This precedent is set with the definition of 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." There are many mandated nutrients and specific levels set in the composition of this product, but this is correctly not highlighted in the definition. As the drink/product for young children under discussion is a similar product but for the next age category and to be Part A and Part B of the same standard, the definitions should be aligned and consistent and should therefore not include the text in square brackets and should read "means a product manufactured for use as a liquid part of the diversified diet of young children."
- 4. The fact that the addition of certain nutrients is mandated, and specific levels set for certain nutrients, does not mean that overall, these products can be considered necessary. It has been agreed by Member States that they are unnecessary no matter their composition. The benefits of these products over and above continued breastfeeding, that is recommended for this age group, has not been shown while there is a body of evidence of the benefits of continued breastfeeding. There is also evidence that these products replace breastmilk in the diet, resulting in a net reduction in the recommended nutritional intake from breastmilk which is contrary to this proposed text. In addition, it must be noted that 3.2 of the standard permits optional ingredients to be added.

This might indeed change the overall profile of the product especially as the evidence regarding a range of ingredients and the ultra-processing of foods is raising a number of concerns. The text is square brackets may in fact be proven untrue and so must be deleted.

- 5. It is critical to note that any contribution of these products to the diets of young children does not apply equally across all countries and as such is misleading. As recognised by the Committee, in some situations these products could make a positive nutritional contribution to the diet. However, in many situations, they are not required and may have a negative impact due to interference with continued breastfeeding and concerns around some of the ingredients and their ultra-processing. The proportion of the children who may be positively or negatively impacted can vary significantly between member states, and while the statement may be accurate for some, for others it will be factually incorrect or misleading. It is therefore inappropriate that a statement that does not apply equally to all Member States be included in the definition in a Codex document and must be removed. If it were to be retained, it should read "...may or may not contribute..." Further, the inclusion of the square brackets text is outside the mandate of Codex Codex should not be setting a universal principle as to the nutritional needs of young children. It is up to Member States to determine what foods / beverages contribute to the nutritional needs of their specific population / sub-population groups.
- 6. When Helen Keller International and many other country delegations and observers strongly stated that this definition should include the fact that these products function as breastmilk substitutes and are defined as such in many countries, this was not accepted as it was stated this was not the case in other countries. It was decided that in order to reach consensus "Codex remain silent on the issue of whether the product was or was not to be described as a breast-milk substitute." We therefore believe that following the same principle in order to reach consensus, this definition should remain silent on whether or not this product may or may not contribute to the nutritional needs of young children.

Thus, the text should read:

Drink/product for young children with added nutrients or Drink/product for young children means a product manufactured for use as a liquid part of the diversified diet of young children.1

1 In some countries these products are regulated as breast-milk substitutes.

Note:

Helen Keller International believes that if the Committee does decide to retain the text in square brackets it would be absolutely necessary that there is additional consultation and discussion on this text due to the fact that as it is currently written it is misleading and undermines prior discussions and consensus by the Committee on similar issues (e.g. use of "formulated").

IBFAN comment on the draft definition of drink/product for young children

IBFAN supports Option 2 with the deletion of the text in square brackets, "which may contribute to the nutritional needs of young children". Option 2 conforms to the Codex Procedural Manual requirements for product definition. These are required only when appropriate: the raw materials from which the product is derived; the processes of manufacture; types and styles of products and type of pack; and additional definitions when these are required. IBFAN notes that the above requirements are met in the following provisions of the draft standard text as follows:

2.1.2; 2.2.1; 3.1.1. IBFAN supports the deletion of the text in square brackets since this gives mothers and parents the impression that these products may be necessary as a contribution to the growth and development of their young child. The World Health Assembly, in Resolution WHA 39.28 determined that these products are not necessary. Hence the definition should not mislead and confer the idea that these products for young children contribute to the nutritional needs of this age group. Although in some unique situations these products may be deemed to be beneficial, this is not the case for the general population of this age group. Additionally, these products are marketed to replace breastfeeding. There is a large body of scientific evidence that the use of these products as breastfeeding replacements have a negative impact on the nutritional intake and status of young children negating the validity of the text in square brackets. Universally governments have

**IBFAN** 

implemented policies to support the sustaining of breastfeeding to two years or beyond. IBFAN is of the opinion that the text in square brackets undermines national policies that support optimal infant and young child nutrition and should not be part of the definition. It is ultimately up to national governmental policies and recommendations to decide on the nutritional relevance of these products. The definition should be aligned with that of the definition of follow up formula for older infants which does not have the additional misplaced qualifier. And should read: Drink/products for young children "with added nutrients" or Drink/product for young children manufactured for use as a liquid part of the diversified diet for young children1. 1. In some countries these products are regulated as breastmilk substitutes.	
IDF commends the work of the eWG and supports keeping the footnote as approved by the Committee in 2016 and listed in the Review of the Standard for Follow-up Formula (CXS 156-1987): Draft Essential Composition and Quality Factors - (at Step 7)	IDF/FIL
IACFO supports Option 2 with the deletion of the text in square brackets, "which may contribute to the nutritional needs of young children". IACFO supports this deletion because the text in brackets could give parents and caregivers the false impression that these products are necessary for optimal growth and development of young children.	International Association of Consumer Food Organizations
ISDI is of the opinion that option 1 should be accepted. ISDI considers it is crucial CCNFSDU42 retains the sentence [which may contribute to the nutritional needs of young children] in the Product definition, section 2.1.1, concerning the role of the product. ISDI considers the product can help contribute or play a role in addressing young children's nutritional requirements when transitioning to a family-based diet. A clear 'stand-alone' definition will allow:-to clarify the meaning of the Standard and fulfill the requirements established in the Codex Procedural Manual concerning the purpose of the definition;-to properly categorize the products for regulators and food business operators to ensure the correct application of the Standard; and -to differentiate it from other beverages. ISDI does not support option 2 as option 2 does not sufficiently define the product category or differentiate it from other beverages. The Standard is a technical document and the requirements relating to the definition set out in the Codex Procedural Manual must be fulfilled.	International Special Dietary Food Industries
UNICEF reaffirms its prior position that the text in square brackets is not necessary or appropriate and should be deleted.	UNICEF
Justification:	
1. The purpose of the definition is to fulfil the requirements of the Codex Procedural Manual that on p57 related to description states: "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."	
Based on the elements of a definition as defined above, UNICEF considers that:	
<ul> <li>The raw materials are currently not covered in the description but are addressed elsewhere in the standard and are therefore not required in the definition.</li> </ul>	
The process of manufacture is covered in the text of 2.1.2, and is not required in the definition.	
The types and styles could be considered covered in part of 2.1.1 namely "for use as the liquid part of the" and part of 2.1.2 namely "so packaged as to prevent spoilage or contamination" It therefore does not need to be covered in the definition.	
In relation to other definitions, 2.2.1 provides a definition for 'young children'. It therefore does not need to be included in the definition.	
UNICEF therefore does not believe that the role or purpose of the product in the diets of young children is necessary to be covered in the description as per the procedural manual.	

Further, any definition should be clear, precise and unambiguous, and does not benefit from a statement about what the product may or may not do, depending on the circumstances – without those circumstances being clearly articulated. If the Committee does decide to retain the text in square brackets, UNICEF believes that further consultation and discussion on this text will be necessary.

2. The text in square brackets should be deleted as the World Health Assembly (WHA), the world's highest health policy setting body, has agreed that these products are unnecessary. By including the text in square brackets, the impression is given by Codex that these products do in fact have a role to play in the diets of young children, which is not the case.

Further, the fact that the addition of certain nutrients is mandated, and specific levels set for certain nutrients, does not mean that overall, these products can be considered necessary. It has been agreed by Member States that they are unnecessary no matter their composition. The benefits of these products over and above continued breastfeeding, that is recommended for this age group, has not been shown while there is a body of evidence of the benefits of continued breastfeeding. There is also evidence that these products replace breastmilk in the diet, resulting in a net reduction in the recommended nutritional intake from breastmilk which is contrary to this proposed text. In addition, it must be noted that 3.2 of the standard permits optional ingredients to be added. This might indeed change the overall profile of the product especially as the evidence regarding a range of ingredients and the ultra-processing of foods is raising a number of concerns. There will therefore be cases where the text is square brackets is proven untrue, and so must be deleted.

- 3. It is critical to note that any contribution of these products to the diets of young children does not apply equally across all countries and as such is misleading. As recognised by the Committee, in some situations these products could make a positive nutritional contribution to the diet. However, in many situations, they are not required and may have a negative impact due to interference with continued breastfeeding and concerns around some of the ingredients and their levels of processing. The proportion of the children who may be positively or negatively impacted can vary significantly between member states, and while the statement may be accurate for some, for others it will be factually incorrect or misleading. It is therefore inappropriate that a statement that does not apply equally to all Member States be included in the definition in a Codex document and must be removed. If it were to be retained, it should read "...may or may not contribute..." Further, the inclusion of the square brackets text is outside the mandate of Codex Codex should not be setting a universal principle as to the nutritional needs of young children. It is up to Member States to determine what foods / beverages contribute to the nutritional needs of their specific population / sub-population groups.
- 4. This definition should follow other, similar definitions for similar products. Mandating certain nutrients to be included or specifying the inclusion or exclusion of certain ingredients or specifying levels in the composition of these products, is a normal part of the Codex standard setting process and does not need to be highlighted in the definition, nor does it mean that the product offers specific benefits. This precedent is set with the definition of 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." There are many mandated nutrients and specific levels set in the composition of this product, but this is correctly not highlighted in the definition. As the drink/product for young children under discussion is a similar product but for the next age category and to be Part A and Part B of the same standard, the definitions should be aligned and consistent and should therefore not include the text in square brackets and should read "means a product manufactured for use as a liquid part of the diversified diet of young children."

Therefore, UNICEF considers that the text should read:

Drink/product for young children with added nutrients or Drink/product for young children means a product manufactured for use as a liquid part of the diversified diet of young children.1

1 In some countries these products are regulated as breast-milk substitutes.

Response from the World Federation of Public Health Associations.

World Federation of Public Health

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We join other groups concerned about the protection of optimal infant and young child nutrition. We believe the text in square brackets is not necessary or appropriate and should be deleted.	Associations
We do not believe it necessary to include the role or purpose of the product in the diets of young children in the description. Our view is informed by the requirements of the Codex Procedural Manual around relevant inclusions in a description.	
A further reason for removing the text in square brackets is that the World Health Assembly (WHA) has agreed these products are unnecessary. Including the text in square brackets gives the impression at Codex that these products do have a legitimate role to play in the diets of young children, which is not the case. Regardless of the nutritional composition of these products they are not a necessary part of the diets of young children.	
If the Committee does decide to retain the text in square brackets, WFPHA believes further consultation and discussion on this text will be necessary.	
The text in square brackets is not necessary or appropriate and should be deleted.	World Public Health
WPHNA does not believe that the role or purpose of the product in the diets of young children is necessary to be covered in the description as per the procedural manual.	Nutrition Association
The text in square brackets should be deleted as the World Health Assembly (WHA), the world's highest health policy setting body, has agreed that these products are unnecessary. By including the text in square brackets, the impression is given by Codex that these products do in fact have a role to play in the diets of young children, which is not the case.	
WPHNA believes that the fact that the addition of certain nutrients is mandated, and specific levels set for certain nutrients, does not mean that overall, these products can be considered necessary. It has been agreed by Member States that they are unnecessary no matter their composition.	
WPHNA thinks the benefits of these products over and above continued breastfeeding, that is recommended for this age group, has not been shown while there is a body of evidence supporting the continuation of breastfeeding.	
There is also evidence that these products replace breastmilk in the diet, resulting in a net reduction in the recommended nutritional intake from breastmilk which is contrary to this proposed text.	
WPHNA believes there will be cases where the text in square brackets is proven untrue, and must be deleted. The point 3.2 of the standards permits optional ingredients to be added. This might indeed change the overall profile of the product especially as the evidence regarding a range of ingredients and the ultra-processing of foods raises concerns.	
Nitrogen to protein conversion factor	
Recommendation 2	
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 'Drink for young children'	added nutrients' and
Brazil could agree with retaining the NCF of 6.25 considering that the confidence in the evidence underlying the proposed conversion factors by JEMNU Expert Panel is not high and that further research is necessary to determine more accurate factors with improved analytical methods:	Brazil
"Option 1: When protein is defined as being only the sum of 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." (pg. 26 of The Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) Nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant formula and follow-up formula)."	
Nevertheless, despite the limitations and uncertainties pointed out by the JEMNU Expert Panel, the conversion factors proposed in the report represent a considerable improvement over the current situation and should not be put away. Therefore, Brazil thinks that the JEMNU Report is highly useful and should be better discussed by CCNFSDU with the aid of the JEMNU aiming the long term-development of improved protein determinations. In that sense, we are of the opinion that a workplan should be discussed by CCNFSDU in conjunction with JEMNU and the stakeholders aiming to gather high-quality data for the determination of the most appropriate NCF for protein sources used in the manufacturing of formulas, and for formulas with different protein sources.	
Burkina Faso is in favour of retaining the NCF of 6.25 in the standard(s) for follow-up formula for older infants and "drinks/products for young children with added nutrients" and "drinks for young children".	Burkina Faso
Comments are both technical and editorial: Canada agrees to retain the NCF of 6.25 in both products as awaiting for a decision on whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein would cause unnecessary delays to completing the review of the Standard for Follow-up Formula. Canada is of the opinion that it is still premature to change the current NCF because there is insufficient data of a high enough quality to justify changing the NCF from 6.25.	Canada
Chile agrees with retaining the NCF of 6.25 of the standard(s) for Follow-up Formula for Older Infants and "Drink/Product for young children with added nutrients" and "Drink for young children".	Chile
The subcommittee agrees with recommendation 2 submitted by the chairs of the eWG. The Nitrogen Conversion Factor (NCF) of 6.25 should be 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".	Colombia
The above is based on the conclusions reached by the NFSDU Subcommittee in 2020, within the framework of the electronic Working Group entitled "Review of the Standard for Follow-Up Formula".	
Recently, alternative methods for estimating the protein content in foods have been evaluated, including direct protein analysis or direct amino acid analysis, which might represent an interesting alternative in the future to obtain more realistic results. For the time being, it is important to use the scientific knowledge that has been compiled. However, the single value (6.25) has long been used to put together standards for different types of products.	
Costa Rica believes the NCF of 6.25 should be 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".	Costa Rica
Egypt supports retention of the NCF footnote*	Egypt
* For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.	
The EU supports the Chairs' recommendation that the Nitrogen Conversion Factor (NCF) of 6.25 is retained in the Standard, due to the following reasons:	European Union

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Based on the conclusions of the JEMNU Expert Panel, it appears that further research would be needed to determine the most appropriate NCFs for protein sources used in the manufacture of formulas that would delay the completion of the review of the Standard for Follow-up Formula.	
• The EU is of the view that a NCF for follow-up formula for older infants and Drink/Product for young children with added nutrients or Drink for young children cannot be considered in isolation from infant formula. Indeed, the conclusions of the JEMNU Expert Panel apply to both follow-up formula and infant formula and currently the same NCF is used for all products. In this context the EU notes that at EU level the default conversion factor of 6.25 is to be used for all products concerned (i.e. for infant formula, follow-on formula and young child formula) to calculate the protein content, irrespective of the protein source. If the NCF of 6.25 was changed for follow-up formula for older infants and Drink/Product for young children with added nutrients or Drink for young children, the NCF for infant formula (and that for formulae for special medial purposes) would also need to be scrutinized and adapted, which could not be done in the context of the work on the review of the Standard for Follow-up Formula.	
A change to the NCF would have a number of significant consequences:	
- it would require the re-opening of the minimum and maximum protein levels and potentially that of other macronutrient levels within the draft revised Standard, which would significantly delay the completion of the work;	
- products complying with the revised compositional requirements would need to be re-labelled and/or re-formulated;	
- there would be no default NCF to use for all permissible forms of protein, as the NCFs proposed by JEMNU cover only dairy and soy-based ingredients;	
- infant formula standard would need to be re-opened.	
Ghana supports the proposed text 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'. The rationale being that there is no strong scientific basis to justify the need for a change.	Ghana
We agree with recommendation 2 submitted by the chairs of the eWG. The NCF of 6.25 should be 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".	Guatemala
Indonesia supports to retain the NCF of 6.25 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' and a different conversion factor for a particular product may be used if scientific justification is provided.	Indonesia
We also agree.	Japan
Kenya supports retention of NCF of 6.25. The conversion factor is applicable to the products	Kenya
We agree that the NCF of 6.25 to be retained in the standards for follow-up formula and the Drink/Product for young children. There is no need to modify the NCF for such products as the protein content and amino acid requirements in the relevant Codex Standards already ensure an adequate protein quantity and quality in the products unless the change is required on the basis of strong scientific perspectives.	Kuwait
Malaysia has no objection with the recommendation 2 to retain nitrogen to protein conversion factor of 6.25 in the standard(s) for Follow-up Formula for older infants and 'Drink/Product for young children with added nutrients' or 'Drink for young children'.	Malaysia
Mali is in favour of retaining the NCF of 6.25 in the standard(s) for follow-up formula for older infants and "drinks/products for young children with added nutrients" and "drinks for young children", in accordance with recommendation 2, annex 1.	Mali

Morocco support this recommendation:	Morocco
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'	
Nepal agrees on the retention of the NCF of 6.25 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' as per Recommendation 2, Appendix I.	Nepal
New Zealand agrees with Recommendation 2, that is to retain the NCF of 6.25 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).	New Zealand
New Zealand is of the view that before any proposal to change to the NCF is considered, a discussion on whether the primary aim of determining protein content is to ensure adequate delivery of amino acids or delivery of total protein should be had first. Furthermore, New Zealand notes the limitations in the evidence underlying proposed different values at this point in time.	
Niger is in favour of retaining the NCF of 6.25 in the standard(s) for follow-up formula for older infants and "drinks/products for young children with added nutrients" and "drinks for young children", in accordance with recommendation 2, annex 1./END	Niger
Nigeria supports 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'	Nigeria
Norway supports the Chairs' recommendation that the Nitrogen Conversion Factor (NCF) of 6.25 is retained in the Standard.	Norway
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 'Product for young children' (Recommendation 2, Appendix I)	Philippines
The Philippines supports that the current nitrogen conversion factor of 6.25 to calculate the protein content from the total crude protein nitrogen content as determined by Kjeldahl is retained in the Standard for Follow-up Formula for Older Infants and Drink/Product for young Children with Added Nutrients and Product for Young Children. It is still considered a practical approach to calculate the protein content of infant formula, follow-up formula for older infants, and Drink/Product for young children with added nutrients and Product for young children.	
Republic of Korea agrees to retain NCF of 6.25 in the standards for Follow-up formula for Older infants and 'drink/product for young children with added nutrients' and 'drink for young children'. Also agrees to EWG that the work on the review of the standard for follow-up formular should not be delayed by the consideration of the 'new' NCF. Especially when the level of evidence are low, the use of a low NCF for soy-based ingredients may create a potential for inaccurate recommended daily protein intake for infants and young children.	Republic of Korea
Senegal is in favour of retaining the NCF of 6.25 in the standard(s) for follow-up formula for older infants and "drinks/products for young children with added nutrients" and "drinks for young children", in accordance with recommendation 2, annex 1.	Senegal
Saudi Arabia agrees to retained NCF in the Standard.	Saudi Arabia
Switzerland supports the Chairs' recommendation that the Nitrogen Conversion Factor (NCF) of 6.25 is retained in the Standard for Follow-up Formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children'.	Switzerland
We support EWG Chair's recommendation to retain the NCF of 6.25 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.	Thailand

The UK agree with the recommendation of the EWG to retain 6.25 as the NCF used in the standard(s) for Follow-up Formula for older infants. The UK would like to note they do not consider these products necessary and they are regulated as general foods in the UK.	United Kingdom
The United States agrees that the Nitrogen Conversion Factor (NCF) of 6.25, as per Recommendation 2, Appendix I, should be retained.	USA
No comment	ENCA
The European Plant-Based Foods Association (ENSA) supports recommendation 2 of the EWG report to retain the NCF of 6.25 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'.	ENSA
ENSA considers that this is a feasible and generally accepted protein conversion factor used by regulatory authorities. Moreover, as outlined at page 10 of the EWG report (as a reply to Question 6), deviating from this NCF would have additional regulatory and market implications.	
Regarding the product name we consider 'drink for young children' as the most appropriate.	
EUVEPRO supports recommendation 2 of the EWG report to retain the NCF of 6.25 the standard(s) for Follow-up Formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children'.	European Vegetable Protein Association
EUVEPRO considers that this is a workable and generally accepted protein conversion factor used by regulatory authorities for Follow-up Formula. Moreover, as summarised in the EWG report, deviating from this NCF will have additional regulatory and market implications.	
Helen Keller International supports the retention of the NCF of 6.25 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' as per Recommendation 2, Appendix I.	НКІ
IDF commends the work of the eWG and supports keeping the footnote* as approved by the Committee in 2016 and listed in the Review of the Standard for Follow-up Formula (CXS 156-1987): Draft Essential Composition and Quality Factors - (at Step 7)	IDF/FIL
* For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.	
UNICEF notes that the Expert panel reported having greater confidence in using the method of analysis that measured the delivery of amino acid (Option1) than that the measured total proteins at this time.	UNICEF
We also note the Expert Panel stated "it has been known for decades that using total nitrogen content with a conversion factor of 6.25 to quantify total protein is imperfect and can lead to a 15–20% error in the actual protein content." (page 6) UNICEF supports the use of the recommended NCF in Option 1 provided by the Expert Panel. If it is not possible to amend the standards affected by these new values at this time, a suggestion for members in the committee may be to facilitate more work to be done on new methods that will provide more clarity and more accurate results to measure protein.	
QUESTION 5	UNICEF
UNICEF agrees that "Drink for young children' should not be considered in isolation to infant formula.	
UNICEF agrees 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') depends on use of option 1 method or option 2 method in determining protein content is to ensure adequate delivery of amino acids or delivery of total protein.	

UNICEF notes that the Expert panel reported having greater confidence in using the method of analysis that measured the delivery of amino acid (Option1) than that the measured total proteins at this time.

We also note the Expert Panel stated "it has been known for decades that using total nitrogen content with a conversion factor of 6.25 to quantify total protein is imperfect and can lead to a 15–20% error in the actual protein content." (page 6)

#### **QUESTION 6:**

UNICEF urges the committee to consider the comments of the Expert Panel when it states that the use of the conversion factor of 6.25 can lead to a 15-20% error in actual protein content (page 6) We would also like to point out that panel provided two options to use as conversion factors addressing the conversion of dairy proteins and soy proteins, the report stated that the experts had more confidence in Option 1, which uses the conversion factor of 6.1 for dairy and 5.7 for soy. UNICEF also notes that other methods are under development such as mass spectrometry and that supports the recommendation that this work continues to add clarity to the committee's overall role of using scientific basis to accurately determine protein content of dairy and soy based formulae.

WPHNA supports the use of the recommended NCF in Option 1 provided by the Expert Panel.

#### **QUESTION 5:**

WPHNA agrees that "Drink for young children' should not be considered in isolation to infant formula.

WPHNA agrees 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') depends on use of option 1 method or option 2 method in determining protein content is to ensure adequate delivery of amino acids or delivery of total protein.

#### **QUESTION 6:**

WPHNA urges the committee to consider the comments of the Expert Panel when it states that the use of the conversion factor of 6.25 can lead to a 15- 20% error in actual protein content (page 6).

WPHNA agrees with the report stating that experts were confident of Option 1 (that uses the conversion factor of 6.1 for dairy and 5.7 for soy).

## World Public Health Nutrition Association