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Agenda Item 4

CX/NFSDU 23/43/4

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

Forty-third Session

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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987): PREAMBLE AND STRUCTURE

Comments in reply to CL 2022/24/OCS-NFSDU

Comments of Australia, Brazil, Burkina Faso, Cambodia, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, Egypt, European Union, Guatemala, Indonesia, Iran, Kenya, Malaysia, Mali, Mexico, Morocco, Nepal, New Zealand, Niger, Nigeria, Norway, Paraguay, Peru, Philippines, Republic of Korea, Saudi Arabia, Senegal, South Africa, Switzerland, Thailand, Uganda, United Kingdom, Uruguay, USA, Viet Nam and AEDA-EFLA, Consumers International, ENCA, HKI, IFT, International Baby Food Action Network, International Special Dietary Food Industries (ISDI), UNICEF

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/24/OCS-NFSDU issued in June 2022. 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.

Annex I

GENERAL COMMENTS	MEMBER / OBSERVER
<p>This standard should be consistent with World Health Assembly resolution 69.9 and resolutions WHA33.32 (1980), WHA34.22 (1981), WHA35.26 (1982), WHA37.30 (1984), WHA39.28 (1986), WHA41.11 (1988), WHA43.3 (1990), WHA45.34 (1992), WHA46.7 (1993), WHA47.5 (1994), WHA49.15 (1996), WHA54.2 (2001), WHA55.25 (2002), WHA58.32 (2005), WHA59.21 (2006), WHA61.20 (2008) and WHA63.23 (2010) on infant and young child nutrition, appropriate feeding practices and other related issues.</p> <p>All products covered by this standard should be defined as breast-milk substitutes and should therefore be subject to the International Code of Marketing of Breast-milk Substitutes.</p> <p>We support and commend the work of the CCNFSDU and stand ready to assist in further consultations on this Standard.</p>	Ecuador
<p>Mexico's comments are based on the recommendations of the World Health Organisation regarding breastfeeding, complementary feeding of infants and feeding of young children: infants should be exclusively breastfed during the first months of life for optimal growth and development and good health. Thereafter, in order to meet nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while continuing breastfeeding until two years of age and beyond. After the age of twelve months, young children are integrated into the family diet through the consumption of suitable, nutrient-rich, home-prepared, and locally available foods.</p> <p>On this particular issue, the regulatory support for the use of infant formula for infants from 0-12 months of age is reiterated in accordance with the provisions of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants CXS 72-1981, as set out below:</p> <ul style="list-style-type: none"> • An infant is understood to be a child not older than 12 months of age, as defined in 2.2 of CXS 72-1981; • 2.1.1 of CXS 72-1981 states that infant formula is 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; • Consequently, such a definition does not delimit a period of use in infants; what it expresses is the period of life in which formula is used exclusively as is done with breast milk (first 6 months of the infant's life), since the nutritional composition of the formula satisfies the nutritional requirements involved in the growth and development that are characteristic of this period of life; • If formula consumption is prolonged beyond 6 months of age, it should be accompanied by complementary feeding in order to meet the evolving nutritional requirements, as occurs also with breast milk; • To provide for this, 9.6.4 of CXS 72-1981 states as a labelling requirement that infants should receive complementary foods, in addition to formula, from an age that is appropriate to their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months; • In this respect, it is striking that this provision was the only one that was not standardised within the subsection providing for "additional labelling requirements" for formula for older infants, which was based on the provisions of CXS 72-1981; • In addition, it is noted that in countries such as Spain, the use of infant formula can be extended to young children. <p>It is noted that "follow-up formula for older infants" differs slightly from the requirements set out in CXS 72-1981 and is therefore considered to be a product that is not necessary as a breast-milk substitute.</p>	Mexico

<p>Likewise, in relation to the “product for young children” it is repeated that this product in this life stage does not play a unique role in providing critical nutrients; therefore, it cannot be considered necessary in order to meet the nutritional requirements of young children compared with other foods that can be included in the normal diet of young children, such as breastmilk, infant formula and cow’s milk or the milk of other animals.</p> <p>Accordingly, no opinion is given on the preamble and no structural approach is taken with regard to the Review of the Follow-up Formula Standard CXS 156-1987.</p> <p>However, it is important to note that the structuring and, where appropriate, the preamble, should not influence the adoption of the two products in question, or in any way induce their use by countries or regions.</p>	
<p>The Philippines is supportive of the timely finalization of the proposed Codex Draft Revised Standard for Follow Up Formula and Product for Young Children. We are strongly in favour of one standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children and inclusion of a preamble as these are consistent with previous Codex Standards for infants and young children and in line with previously submitted Philippine Positions. We are of the opinion that this structure will facilitate a more efficient process to move forward at this final stage of standard setting since work and discussion in the draft standard have lasted for over a decade.</p>	Philippines
<p>The European Food Law Association (EFLA) members are professionals and/or lawyers specialized in Food law as well as academics, from the majority of EU and many non-EU countries. EFLA does not represent or defend any specific interest and generally does not take positions on specific product matters, but is happy to contribute to the general debates from a horizontal legal perspective.</p> <p>It is therefore happy to submit the following comments.</p> <p>The review of the Standard for follow-up formula arrives at its final stage. EFLA welcomes this achievement and respectfully submits the following to the request for comments on the structure of the standard and on the need or not for a preamble.</p>	AEDA-EFLA
<p>IBFAN is of the opinion that the standard has not been completed. There remain unresolved areas of the standard, such as sodium levels for drinks for young children, methods of analysis for sweetness and the lack of consensus on the use of flavourings in drinks for young children.</p> <p>The responses to the questions presented in this discussion paper will be analysed and presented in a paper for CCNFSDU43.</p>	IBFAN
SPECIFIC COMMENTS	
STRUCTURE	
Now that the standard has been completed, please indicate your preferred structure approach and clearly state why you do, or do not, support each option:	
<p>Australia has previously supported Option b – two separate standards based on:</p> <ul style="list-style-type: none"> • CCNFSDU agreeing there is a recognised point of differentiation between Follow-up Formula for Older Infants and the product for Young Children (i.e. at 12 months of age) due to different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to that of young children; and • in Australia products for young children are regulated separately as special dietary use products to be consumed in situations where energy and nutrient intakes are inadequate and are not considered a breast milk substitute. However from a pragmatic perspective Australia could support Option a, i.e. one standard with two parts. 	Australia

<p>Brazil supports option A, i.e. one standard with two separate parts covering Follow-up Formula for Older Infants and Product for Young Children since both products are considered breast-milk substitutes as clarified by WHO: “breast-milk substitutes should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks).” (https://apps.who.int/iris/bitstream/handle/10665/275875/WHO-NMH-NHD-18.11-eng.pdf?sequence=1&isAllowed=y).</p> <p>We are also of the opinion that this option can accommodate the role of the different products in the diet and different compositions.</p> <p>Brazil's comments for item "b": Brazil does not support this option considering the issues expressed in the answer for option A.</p> <p>Brazil's comments for item "c": Brazil does not support this option considering the issues expressed in the answer for option A.</p> <p>Brazil's comments for item "d": Brazil does not support this option considering the issues expressed in the answer for option A.</p>	Brazil
<p>The structure preferred by Burkina Faso is “a. One standard in two parts: Part A covers the follow-up formula for older infants and part B covers the product for young children”.</p> <p>The justification for choosing a standard in two parts is as follows:</p> <ol style="list-style-type: none"> 1. The text of the final definition of the standard acknowledges that the two groups of products are recognised and used as substitutes for breast milk as the liquid element of a diversified diet and, therefore, they should be included in a single standard in two parts. The follow-up formula for older infants (6-12 months) is specifically defined as a substitute for breast milk: “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.” The definition of the product for young children includes an important footnote which must always be read as part of the definition and which recognises that many countries regulate these products as substitutes for breast milk: “Drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children designates a product manufactured for use as the liquid element of a diversified diet for young children¹”. ¹ <i>In some countries, these products are regulated as substitutes for breast milk</i>. On the basis of these definitions and taking into consideration the fact that they are also defined as substitutes for breast milk in the International Code of Marketing of Breast Milk Substitutes (1981) (the Code), which is confirmed by resolution 69.9 (2016) of the World Health Assembly (WHA), it is logical for these products to be included in the same two-part standard. This will also make it easier to implement the Code, the standards of the Codex and the national legislation consistently. 2. Although infant formulas are needed in certain cases, follow-up formulas for older infants and products for young children are not, as the World Health Assembly confirmed in its document WHA 39.28: “The practice being introduced in some countries of providing infants with specially formulated milks (so-called “follow-up milks”) is not necessary”. To avoid any confusion, it is useful to distinguish between products that are sometimes necessary (infant formulas), which have their own standard, and products that are useless (follow-up formulas for older infants and products for young children), which should also have their own standard. 3. The division of a single standard for products with a similar concept into two parts on the basis of the age-related difference in composition is logical and a precedent has been set in the standard for infant formulas (CODEX STAN 72-1981), which has been divided into two parts, section A: Standard for Infant Formula and section B: Formula for Special Medical Purposes Intended for Infants. Although these two products are intended for two sub-groups which are not the same as older infants/young children and although they have a very different composition, they form a single standard. The situation should be the same for the standard concerning follow-up formulas, because although follow-up formulas intended for older infants and products for young children have very different compositions, they are based on a similar concept and, therefore, make up two sections of the same standard. In addition, there is no justification for separating the two parts of the standard into two distinct standards. Their definition is clear; 	Burkina Faso

they have the same objective but for different age groups. Furthermore, both form a liquid element of a progressively diversified diet. Also they do not constitute complementary foods and, therefore, do not need a separate standard.	
<p>CAMBODIA strongly supports ‘a. One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.’, with the following reasons:</p> <ol style="list-style-type: none"> 1. Both products are recognized and used as breastmilk substitutes. The current standard contains reference to both products being breastmilk substitutes and their use as a liquid part of the diversified diet. Both products are also defined as breastmilk substitutes in the International Code of Marketing of Breast-milk Substitutes (1981) (the Code) as confirmed by World Health Assembly Resolution 69.9 (2016). As no distinction is made between the products in the Code, no such distinctions are likely to be made by Member States implementing the Code and subsequent WHA resolutions into national laws and regulations. One standard with two parts would facilitate implementation coherence between the Code, Codex standards and national laws. 2. Both follow-up formulas and milk products for young children have been deemed unnecessary by the World Health Assembly (WHA 39.82). Making further distinctions between these two products by having them in separate standards may cause further confusion about the roles they play in infant and young child diets. 3. The STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72 – 1981 sets a precedent of a standard addressing two conceptually similar products (that may be necessary for infants who are not breastfed). It follows that these two products (that are not necessary) also be contained within one standard divided into relevant parts. 	Cambodia
Canada has in the past noted a preference for option b since the Product for Young Children is so different compositionally. Canada prefers option b, however, given there are pros and cons for both options, Canada would not be opposed to option a; having one standard with two parts.	Canada
<p>Chile’s proposal is option a:</p> <ol style="list-style-type: none"> a. One standard with two parts: part A for follow-up formula for older infants and part B for the product for young children. <p><u>Justification</u> Most of the provisions and requirements of the standard are aligned, and the preamble section is relevant for both products. Therefore, we think that this structure makes it clearer to understand the context, the provisions and the application of the regulation.</p>	Chile
<p>Option a) - This option is in line with the way the Standard was developed and drafted, with a clear distinction between the two products, emphasising the clear separation between part A and part B. They also note that the current format provides for numerous cross-references between parts A and B and that having both parts under one Standard makes it easier to read the respective requirements.</p> <p>Likewise, in the framework of regulatory simplification that has been encouraged worldwide, it is considered appropriate to consolidate the requirements of both products in a single standard with two parts.</p>	Colombia
While clarity is provided that the responses to the issues raised in this discussion paper will be discussed and submitted to the 43 rd Session of the CCNFSDU for consideration, Costa Rica supports option 1a. It considers that this option is in line with the way the standard has been developed, so that the two products, referred to in section A and section B, are clearly distinguished. The current format establishes cross-references between sections A and B, so having both parts under one standard would facilitate the reading of the respective requirements.	Costa Rica
As for the structure, we have no objection to the adoption of any of the options	Cuba

Ecuador agrees that the structure of the standard should be that of a single standard with two parts; considering that the 6-12 month and 12-36 month categories are conceptually similar, they are breast-milk substitutes, and should be considered as such.	Ecuador
<p>Egypt supports Option 1: One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.</p> <p>Rational:</p> <ul style="list-style-type: none"> -- Egypt considers that both products are breast-milk substitutes. -- The two products have the same function as to serve as a liquid part of the diversified diet of older infants and young children during the complementary feeding period. -- Compositional differences are not a justification for two separate standards. -- Other Codex standards and guidelines (such as the Standard for Cereal-Based Foods for Infants and Young Children (STAN 74-1981) are applicable to two distinct age groups. 	Egypt
<p>The European Union (EU) supports option a, one standard with two parts.</p> <p>As diets progressively diversify, the role of the products in question also changes over time in the diet of infants and young children, however, the products are conceptually similar (i.e. they are liquid elements in the diversified diet of older infants and young children). The EU is of the view that one standard sufficiently accommodates the role of the products in the diet of infants and young children by having two separate parts in it. This option would be consistent with the approach taken in the Infant Formula Standard (which has Part A covering infant formula and Part B covering formulas for special medical purposes intended for infants, both product types with differing objectives and compositions) as well as with the approach taken in other Codex standards and guidelines, such as the Standard for Cereal-Based Foods for Infants and Young Children (CXS 74-1981) and the Guidelines on Formulated Complementary Foods for older infants and young children (CXSG 8-1991), which are applicable to both infants and young children. Furthermore, option a is in line with the approach already taken before by having a Standard for Follow-up formula for the age range of 6–36 months, while a point of differentiation being included now at 12 months.</p> <p>As regards option b, the EU wishes to reiterate that the European Food Safety Authority in its opinion of 2013 noted that these products are one of the means to increase intakes of certain nutrients at risk of inadequacy for some young children, but 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. The EU does therefore not support to have two separate standards for Follow-up Formula for older infants and products for young children.</p>	European Union
Guatemala indicates that after reviewing in detail the results of CCNFSDU42 and considering that the standard is practically finalised, following the line that both products are part of the diversification of the diet of the two age groups, we support option a): one standard divided into two parts: part A referring to follow-up formula for older infants and part B referring to formula for young children.	Guatemala
Indonesia is of the opinion that there should be two separate standards for Follow-up Formula for Older Infants and Product for Young Children to allow flexibility on establishing and updating the requirements for each product.	Indonesia
Option B is preferred, (i.e. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children), despite from leading to a very large and complicated standard; because the important differences in daily requirements and in UL between	Iran

<p>old infant and young children. Furthermore, the formula may play the role of breast milk substitute for old infants while it does not have the same role for the young children, necessarily. So, their composition may not be totally as the same as each other.</p>	
<p>Kenya strongly support option (a) where the two parts of the standard will be in one standard. We do not support the Committee to open up discussion on new/different structures other than what the committee has extensively discussed as provided in options (a) and (b) as stated in the questions.</p> <p><u>Justification:</u> Kenya supports option (a) given that the products under discussion are conceptually similar in both formulation, processing as well as consumption. We also take into consideration that this committee has previously published standards (infant formula) using this format and thus it would be ideal for the committee to be consistent in its work. Further, the use and referencing of the standards will be easier for the users when they are published in one standard. We also take note that publishing the standard as one will not contravene any provisions/requirement of the Procedural Manual.</p>	Kenya
<p>b. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children.</p> <p>The rationales for separate standards older infants and young children are as follows:</p> <p>a. The nutritional requirements of older infants and young children are different</p> <p>b. The feeding pattern for older infants and young children are also different. The older infants take small to moderate amount of weaning diet, and milk is still very much a main source of nutrition. Follow-up formulas should be nutritionally adequate to meet these needs. Young children, on the other hand, generally eat family foods, while milk is a wholesome addition to the child's regular diet.</p> <p>c. There are differences in the activity, physiological, growth and development pattern between older infants and young children.</p> <p>Indeed, it would be a misnomer to call a product for young children up to three years old "follow-up". In terms of language or common use, the term "follow-up" is inappropriate for foods for young children.</p> <p>Almost all dietary guidelines in the world recommend the consumption of milk by children and all age groups. It is in line with this recognition that milk is still be a required and wholesome food for growing children in addition to family food, that Malaysia proposes that a nutritious milk product should be made available for young children above 1 year of age and should be distinctly different in term of labelling.</p> <p>Further more, it can be noted that the issue on whether the products are breastmilk substitutes have been largely resolved. CCNFSDU40 had agreed that follow-up formula for older infants is a breastmilk substitute and as such this has been included in the product description (Section 2.1.1 of the Standard). On the other hand, CCNFSDU41 had agreed that the standard would remain silent on classifying product for young children as a breastmilk substitute but noted that in some countries they are regulated as such.</p> <p>In conclusion, Malaysia is of the opinion that it would be more logical, more useful and less confusing to the consumer and the regulatory authorities if there are two separate products, with distinctly different nutrient composition and clearly labelled.</p>	Malaysia
<p>The structure preferred by Mali is "a. One standard in two parts': Part A covers the follow-up formula for older infants and part B covers the product for young children".</p> <p>The justification for choosing a standard in two parts is as follows:</p> <p>1. The text of the final definition of the standard acknowledges that the two groups of products are recognised and used as substitutes for breast milk as the liquid element of a diversified diet and, therefore, they should be included in a single standard in two parts. The follow-up formula for older infants (6-12 months) is specifically defined as a substitute for breast milk: "The follow-up formula for older infants designates a product manufactured for use</p>	Mali

<p>as a substitute for breastmilk as a liquid element of a diet for older infants when complementary feeding is introduced and progressively diversified.” The definition of the product for young children includes an important footnote which must always be read as part of the definition and which recognises that many countries regulate these products as substitutes for breast milk: “Drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children designates a product manufactured for use as the liquid element of a diversified diet for young children¹”. “¹ In some countries, these products are regulated as substitutes for breast milk”. On the basis of these definitions and taking into consideration the fact that they are also defined as substitutes for breastmilk in the International Code of Marketing of Breast Milk Substitutes (1981) (the Code), which is confirmed by resolution 69.9 (2016) of the World Health Assembly (WHA), it is logical for these products to be included in the same two-part standard. This will also make it easier to implement the Code, the standards of the Codex and the national legislation consistently.</p> <p>2. Although infant formulas are needed in certain cases, follow-up formulas for older infants and products for young children are not, as the World Health Assembly confirmed in its document WHA 39.28: “The practice being introduced in some countries of providing infants with specially formulated milks (so-called “follow-up milks”) is not necessary”. To avoid any confusion, it is useful to distinguish between products that are sometimes necessary (infant formulas), which have their own standard, and products that are useless (follow-up formulas for older infants and products for young children), which should also have their own standard.</p> <p>3. The division of a single standard for products with a similar concept into two parts on the basis of the age-related difference in composition is logical and a precedent has been set in the standard for infant formulas (CODEX STAN 72-1981), which has been divided into two parts, section A: Standard for Infant Formula and section B: Formula for Special Medical Purposes Intended for Infants. Although these two products are intended for two sub-groups which are not the same as older infants/young children and although they have a very different composition, they form a single standard. The situation should be the same for the standard concerning follow-up formulas, because although follow-up formulas intended for older infants and products for young children have very different compositions, they are based on a similar concept and, therefore, make up two sections of the same standard. In addition, there is no justification for separating the two parts of the standard into two distinct standards. Their definition is clear; they have the same objective but for different age groups. Furthermore, both form a liquid element of a progressively diversified diet. Also they do not constitute complementary foods and, therefore, do not need a separate standard.</p>	
<p>Morocco has chosen option b. Two separate standards: one standard for follow-up formulas intended for older infants and one standard for products for young children. The composition, nutritional quality and labels can be different. This could cause confusion for consumers.</p> <p>This is in accordance with the observations on structure made by the members of the electronic working group in 2018.</p>	Morocco
<p>Nepal strongly supports option (a) - one standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children. The justification for selecting option (a) is as follows:</p> <ol style="list-style-type: none"> 1. The current revision in Mother’s Milk Act of Nepal recognizes both products as breastmilk substitutes. International Code of Marketing of Breastmilk Substitute (1981) (the Code) also defines both follow-up formula and drink for young children as breastmilk substitute, as confirmed by World Health Assembly Resolution 69.9 (2016). Therefore, these two products are recognized conceptually same as breast-milk substitutes and should be included in one standard. As countries like Nepal often follow the Code and Codex to develop their own laws and standards, one standard with two parts will facilitate implementation coherence between the Code, Codex standards and national standards. 2. Having one standard with two different parts is also consistent with the approach taken in the Infant Formula Standard (CODEX STAN 72-1981) which has been divided into two parts, Section A: Standard for infant formula, and Section B: Formula for special medical purposes intended for infants. 	Nepal

<p>3. While infant formula is considered necessary in some medically indicated cases, both follow-up formula and drink/product for young children are considered not necessary by World Health Assembly Resolution 39.28. Therefore, to avoid any confusion, two separate standards for some time necessary infant formula and unnecessary products (follow-up formula and drink/product for young children) is important.</p>	
<p>New Zealand supports option a). New Zealand is keen to maintain the status quo, that is one standard. We see no clear reason to separate the standard into two separate standards and consider that dividing the standard into two parts adequately provides for the different compositional requirements for both product categories. Further, the labelling provisions for both product categories are aligned and therefore we support keeping these products in the one standard.</p>	New Zealand
<p>Niger is in support of point a, in other words, a standard with two parts: Part A covers the follow-up formula for older infants and part B covers the product for young children.</p> <p>The justification for choosing a standard in two parts is as follows:</p> <p>1. The text of the final definition of the standard acknowledges that the two groups of products are recognised and used as substitutes for breast milk as the liquid element of a diversified diet and, therefore, they should be included in a single standard in two parts. The follow-up formula for older infants (6-12 months) is specifically defined as a substitute for breast milk: “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.” The definition of the product for young children includes an important footnote which must always be read as part of the definition and which recognises that many countries regulate these products as substitutes for breast milk: “Drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children designates a product manufactured for use as the liquid element of a diversified diet for young children¹”. “¹ In some countries, these products are regulated as substitutes for breast milk”.</p> <p>On the basis of these definitions and taking into consideration the fact that they are also defined as substitutes for breast milk in the International Code of Marketing of Breast Milk Substitutes (1981) (the Code), which is confirmed by resolution 69.9 (2016) of the World Health Assembly (WHA), it is logical for these products to be included in the same two-part standard. This will also make it easier to implement the Code, the standards of the Codex and the national legislation consistently.</p>	Niger
<p>Nigeria supports option a: One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.</p> <p><u>Rationale:</u> Nigeria has consistently maintained that both products (Follow-up Formula for Older Infants and Product for Young Children) are recognized, used, and regulated as breastmilk substitutes. They are also clearly defined as breast milk substitutes in the International Code of Marketing of Breast-milk Substitutes (1981) as clarified by World Health Assembly Resolution 69.9 (2016). Further, from the final definition in the standard there is acknowledgement that both products are recognized and used as breastmilk substitutes: “Follow-up formula for older infants means a product, manufactured for use as a breast-milk substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.” In the second category, that is, product for young children, the definition recognizes and acknowledges that the products are regulated as breast milk substitutes in some countries: “Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children 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”. Nigeria is one of such countries. In view of the above, Nigeria is of the opinion that it is logical for both products to remain within the same standard with two relevant parts as they are recognized, used, and regulated as breast milk substitutes. It would also make for alignment and coherence of the Codex standards, the Code, and national laws.</p>	Nigeria

<p>Nigeria notes that while infant formula is sometimes necessary, there is a clear statement from the World Health Assembly (WHA 39.28) that follow-up formula and milk products are not necessary in the diets of older infants and young children. It is therefore more valuable to retain these products (Follow-up Formula for Older Infants and Product for Young Children) within one standard in their relevant parts, to avoid creating further confusion that may arise regarding the roles they play in the diets of older infants and young children if presented as separate standards.</p> <p>It is important to also mention that a precedent to this standard structure already exists with the Standard for Infant Formula and and Formulas for Special Medical Purposes intended for Infants (CODEX STAN 72-1981) which is structured as one standard with two parts, Section A: Standard for infant formula, and Section B: Formula for special medical purposes intended for infants. Nigeria is of the opinion that the same should be applicable to the structure for the follow-up formula standard; both products are defined as a liquid part of the diversified diet of older infants and young children and both are recognized, used, and regulated as breastmilk substitutes with a point of differentiation at 12 months.</p>	
<p>We support option a: One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.</p> <ul style="list-style-type: none"> • Both Follow-up Formula for older infants and Product for Young Children are recognized and used as breastmilk substitutes, as clarified in WHA 69.9 and Guidance on ending the inappropriate promotion of foods for infants and young children. These products serve the same purpose, but for different age groups. • Both are, however, unnecessary products, according to WHA 39.82, as opposed to the sometimes-necessary products infant formula (for infants who are not breastfed). • Following the above, it is appropriate to include Follow-up Formula for older infants and Product for young children in the same standard, however separate from the infant formula products, which have their own standard. Separation of the unnecessary and sometimes-necessary products into two standards will contribute to avoid confusion about the roles these products play in infant and young child diets. • Precedent for including two similar products in the same standard, has been set in the Infant formula standard, which includes two conceptually similar products (both sometimes necessary). In a similar way, Formula for older infants and Product for Young Children (both not necessary) should also be contained within one standard divided into relevant parts. 	Norway
<p>We support option 2: two separate standards</p>	Paraguay
<p>After careful consideration of the results of CCFSDU42 and taking into account that the standard is almost finalised, we support option a): one standard with two parts: part A referring to follow-up formula for older infants and part B referring to products for young children as a more pragmatic way forward because the current format establishes numerous cross-references between parts A and B and having both parts under one Standard makes it easier to read the respective requirements.</p>	Peru
<p>The Philippines supports Option A-One standard with two parts: Part A covering Follow-up Formula for Older Infants, and Part B covering Product for Young Children. There is logic to divide a single standard of similar products in concept into two parts, based on age-related compositional differences. There have been precedents in single standards with two parts.</p> <p>This structure is similar to the Codex Standard for Infant Formula which has Part A covering Infant Formula and Part B covering Formulas for Special Medical Purposes Intended for Infants, both product types with different objectives and compositions. Option A is also consistent with the Standard for Cereal-Based Foods for Infants and Young Children (CXS 74- 1981) and the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991) since both guidelines apply to two distinct age groups. These are both stand-alone standards applicable to two distinct age groups, namely, older infants and young children (1,2). Following the same approach, Option A can accommodate the different names, definitions,</p>	Philippines

<p>compositions, and labelling requirements of the two products. This option is in line with the way the proposed Standard is developed and elaborated with a clear distinction between the two products emphasized by the clear separation between Part A and Part B.</p> <p>From the standpoint of nutrition science, Option A recognizes both:</p> <ol style="list-style-type: none"> 1. The point of differentiation at 12 months of age owing to variation of energy and nutrient requirements between older infants (6–11 months) and young children (12–36 months) as laid down in the Philippine Dietary Reference Intakes and international nutrient-based dietary standards (3), and 2. The distinct dietary pattern of older infants compared to that of young children <p>Lastly, there is no significant reason for separate standards which would unduly highlight significance of Product for Young Children. Option A would also facilitate timely finalization of this Codex Standard and coherence in the subsequent implementation once approved with International Code of Marketing Breast-milk Substitutes and national laws.</p>	
<p>'Be consistent' is often used when we work on standards in the committee. I would like to keep the same manner when we decide on the structure of the revised CXS 156-1987.</p> <p>One standard with two parts is consistent with the approach taken in the infant formula standard: Part A infant formula and Part B formulas for special medical use intended for infants, both with different objectives and compositions. The same approaches have already been taken for composition and labeling provision during the revision process for the past 10 years.</p> <p>Formulas we discuss in this standard are not a 'sole source of nutrition.': it is rather a liquid part of the diversified diet of older infants and young children during the complementary feeding period. Because it is a 'follow-up' part of the diet, it may not nutritionally absolute. The Republic of Korea views it as unnecessary to set a strict standard separately even though the nutritional composition of each age group is different.</p>	Republic of Korea
<p>The Kingdom of Saudi Arabia supports option (a). One standard for both Follow-up Formulas with two parts: (1) Older Infants; (2) Product for Young Children.</p> <p>Older Infants (6 -12 m) and Young Children (1-3 Y) have different nutritional requirements.</p>	Saudi Arabia
<p>Senegal has chosen point a, a standard with two parts. Part A covers the follow-up formula for older infants and part B covers the product for young children.</p> <p>The justification for choosing a standard in two parts is as follows:</p> <p>The text of the final definition of the standard acknowledges that the two groups of products are recognised and used as substitutes for breastmilk. They should be included in a single standard with two parts.</p>	Senegal
<p>South Africa supports option (b): Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children.</p> <p><u>Rationale:</u> The standards are intended for two different products which are for different age groups with differing nutritional requirements.</p>	South Africa
<p>Switzerland supports option b with two separate standards, as this option offers more flexibility: with two separate standards, it will be possible to revise one, the other or both, which will facilitate an accurate and faster revision process in the future of the CCNFSDU.</p>	Switzerland

<p>Furthermore, these two categories of products are considerably different, one is considered a substitute for breast milk, while the other is not and the requirements for the composition of products for young children are considerably lower.</p>	
<p>We agree with option B that two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children.</p> <p>In view of the above, we are of the opinion that the approach clearly differentiates and recognises that the two products are very different as to their composition and role in the diet for different age groups, as well as the different nutritional requirements of older infants and young children. In addition, different names, definitions, purposes, composition and labelling provide the basis for two separate standards.</p> <p>Moreover, this option would have no procedural implications and would not affect the timeline.</p>	Thailand
<p>Uganda supports Option 1a: One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.</p> <p><u>Justification:</u> The option is consistent with the approach taken in the other Codex standards like Standard for Cereal-Based Foods for Infants and Young Children (STAN 74-1981), Guidelines on Formulated Complementary Foods for older infants and young children (CAC/GL 8-1991).</p> <p>Additionally, with an example on the Infant Formula Standard; Part A Infant Formula and Part B Formulas for Special Medical Purposes Intended for Infants, the standard has both parts differing in the objectives and compositions of nutrients.</p> <p>The two parts of the standard specify two products, which are abstractly similar and serve as a liquid part of the diversified diet of older infants and young children during the complementary feeding period and both products are breast-milk substitutes. Further, Uganda notes that option 1a would allow for ease access of both parts of the standard by the users, especially the industries producing both products.</p>	Uganda
<p>The UK's preferred approach would be for Option 1a as this would be consistent with the approach taken in in other Codex standards and guidelines such as the Standard for Cereal-Based Foods for Infants and Young Children (STAN 74-1981) and the Guidelines on Formulated Complementary Foods for older infants and young children (CAC/GL 8-1991) and the Infant Formula Standard; Part A Infant Formula and Part B Formulas for Special Medical Purposes Intended for Infants, which are similar products with differing objectives and compositions.</p> <p>However, the UK is able to support either approach to the structure "One standard with two parts" or "Two separate standards" on the basis that either option differentiates the different products (Follow-up Formula for Older Infants and Product for Young Children) role in the diet of the specific population groups - older infants and young children and the different compositional requirements which are needed to meet the nutritional requirements for these age groups.</p>	United Kingdom
<p>a. One standard with two parts: part A for follow-up formula for older infants and part B for the product for young children.</p> <p>Uruguay supports option A, that is to say, one standard with two separate parts: part A for follow-up formula for older infants and part B for the product for young children. This structure is consistent with existing national regulations on the subject, in which both products are considered to be breastmilk substitutes. Ministerial Order 62/017 which includes the "National Breastfeeding Standard", the "Guide for the use of infant formula for infants up to 12 months" and the "Guide for complementary feeding of children from 6 to 24 months"; establishes that "it is necessary to establish and update the standards for the implementation and development of actions that protect, promote and support exclusive breastfeeding on demand for children up to six months of age and breastfeeding with timely, adequate, harmless, safe, perceptive and properly administered complementary feeding up to 2 years of age or beyond, as decided by the mother-baby binomial, as well as the development of strategies together with the families and all community players, that contribute to the national goal." It is clear from this text that both products are intended for the same age group as those targeted by the</p>	Uruguay

<p>measures laid down in Order 62/017. The aforementioned Order also defines “Breastmilk substitute” as “Any food marketed or otherwise presented as a partial or total substitute for breastmilk, whether or not it is suitable for that purpose”. This definition is in line with what is established by the WHO: “should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks)” https://apps.who.int/iris/bitstream/handle/10665/275875/WHO-NMH-NHD-18.11-eng.pdf?sequence=1&isAllowed=y</p> <p>There are precedents in national legislation that recognise formula for older infants and products for young children as breastmilk substitutes, for example, Decree No. 234/018 REGULATION OF LAW 19,530, ON THE INSTALLATION OF BREASTFEEDING ROOMS, establishes in its articles 2 and 3 the following:</p> <p>“Comply with the International Code of Marketing of Breast-milk Substitutes (ICMBS/UNICEF/WHO 1981) and its amendments, as well as the National Breastfeeding Standard of the Ministry of Public Health, Ministerial Order No. 62/2017 of 19 January 2017, which prohibit direct or indirect advertising or promotion (posters, objects, gifts, information directed at women and families) of companies or laboratories that manufacture or distribute infant formula or other foods or drinks for infants and young children, as well as bottles, soothers and teats.”</p> <p>b. Two separate standards: one standard for follow-up formula for older infants and one standard for the product for young children.</p> <p>Uruguay does not agree with this option, as it does not contemplate the issues described in the observations on option A.</p> <p>c. You can support either approach.</p> <p>Uruguay does not agree with this option as it does not contemplate the issues described in the observations on option A.</p> <p>d. If you support a different structural approach, describe and justify it</p> <p>Uruguay does not support a different approach.</p>	
<p>The United States has considered the options for approaching the structure of the draft standard that has two parts (i.e., Part A – Follow up Formula (FUF) for Older Infants and Part B - Drink/Product for Young Children) and feels there are merits to a number of the options provided above.</p> <p>Part A of the draft standard (FUF for Older Infants) reflects the updates to the existing Codex Standard for FUF (CXS 156-1987). Currently, the product of the existing Codex Standard for FUF (CXS 156-1987) does not have a nutrition composition sufficient to meet all the nutritional needs of older infants ages 6-12 months. The Essential Composition of the product of the draft standard has been amended to make the product suitable as a sole source of nutrition for older infants and is intended be used as a breastmilk replacement. Thus, the product of the new proposed draft standard is an infant formula designed to contribute to the nutritional needs ages 6-12 months as they transition to solid foods.</p> <p>If the Committee chooses to split the existing draft standard into separate standards, then the United States would recommend the Committee consider Option D – support a different structure approach. The United States believes that it would be most appropriate to incorporate Part A of the draft standard (FUF for Older Infants) into the existing Infant Formula Standard (CXS 72-1981) so that all infant formula texts are contained in a single Codex standard. Part B of the draft standard (Drink/Product for Young Children) would then become a separate and independent Codex standard as the product of this part of the draft standard is not suitable for use as a sole source for nutrition but is intended to be incorporated into the diet patterns of young children. However, the United States is hesitant to recommend or support this approach because opening the Infant Formula Standard (CXS 72-1981) could create significant delays in completing the Committee’s work.</p>	<p>USA</p>

<p>The United States supports maintaining the current structure as a pragmatic approach to facilitating the Committee's work. In our view, there is no real value in separating the standard into two independent standards and, therefore, the United States supports Option A – one standard with two parts.</p>	
<p>Vietnam supports option 1 such as: One standard with two parts: Part A covering Follow up Formula for Older Infants and Part B covering Product for young Children.</p> <p><u>Rationale:</u> Having one standard with two parts A and B will facilitate for users.</p>	Vietnam
<p>The current draft standard is composed of two parts, one (part A) devoted to follow-up formula for older infants (from 6 to 12 months) and the other (part B) devoted to products for young children (from 12 to 36 months), the name of the product remaining to be decided. Since it has been acknowledged that these two parts describe two different categories of products, destined to two different age groups, it seems more clear and more coherent, from a legal point of view, to have two separate standards. This would facilitate further references to the standards, in national laws as well as in private transactions when they refer to Codex standards.</p> <p>Therefore, EFLA would favour Option 2, i.e. two separate standards.</p> <p>However, considering that the present document has favoured option 1 so far (one standard in two parts), and considering that there does not seem to be obvious legal consequences or strong legal obstacles to this structure, provided both parts are very clearly distinguished (see below re. preamble), EFLA could accept one standard in two parts.</p>	AEDA-EFLA
<p>CI supports option 1d. Our FIRST choice regarding structure is to have ONE standard that is divided into 4 parts. With a section dedicated to 1) infant formula, 2) formulas for special medical purposes, 3) follow-up formula and 4) drinks for young children. This is the most effective structure and will serve most useful for implementation of legislation at the national level.</p> <p>If 1d is not chosen our SECOND choice is to have one standard with two parts, which is option 1a. The option we are most opposed to is option 1b which calls for two separate standards. The creation of two separate standards obviates the fact that follow up formula for older infants AND follow up formula for young children play a very similar role in the diet and both are breastmilk substitutes. Thus, separating these products into two separate standards belies their similarities. The International Code of Marketing of Breast-milk substitutes and the WHA Resolution 69.9 also considers both products breastmilk substitutes and makes no distinction between them.</p>	Consumers International

<p>ENCA is strongly opposed to Option 1.b: This option proposes the creation of two separate standards for Follow-Up Formula and Drinks for Young Children. Both products are recognized as breastmilk substitutes by the International Code of Marketing of Breast-milk Substitutes and World Health Assembly Resolution 69.9 (2016).</p> <p>ENCA's favorite is Option 1.d: one standard, sub-divided into four sections covering Infant Formula, Formulas for Special Medical Purposes, Follow-up Formula and Drinks for Young Children would facilitate more efficient and simplified law-making. As New Zealand has identified in Table 1, numerous provisions are common to ALL FOUR categories.</p> <p>Second best would be Option 1a. one standard in two parts, covering Follow-up Formula and Part B for Drinks for Young Children. However if this is the preferred option, we advocate that each standard contain a footnote to the title referencing the paired/corresponding/associated Codex standard and recommending that governments address products in both standards in national legislation or regulations so that at national level, all four categories should be covered under one national standard.</p> <p><u>Rationale:</u> The International Code of Marketing of Breast-milk Substitutes (1981) and World Health Assembly Resolution 69.9 (2016) are clear that both product categories function as breastmilk substitutes and no distinction is made between them. Recommendation 2 of World Health Assembly 69.9 Guidance on ending the inappropriate promotion of foods for infants and young children “ states “...It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products” [milks specifically marketed for feeding infants and young children up to the age of 3 years or older].</p> <p>ENCA is of the opinion that the standard has not been completed. There remain unresolved areas of the standard, such as sodium levels for drinks for young children, methods of analysis for sweetness and the lack of consensus on the use of flavourings in drinks for young children.</p>	<p>ENCA</p>
<p>Helen Keller International’s preferred structure is ‘a. One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.’</p> <p>The justification for the selection of one standard with two parts is as follows:</p> <p>1. The final definition text of the standard acknowledges both groups of products as being recognized and used as breastmilk substitutes as a liquid part of the diversified diet and therefore, they should be included in one standard as two parts. Follow up formula for older infants (6-12 months) is directly defined as being a breast-milk substitute: “Follow-up formula for older infants means a product, manufactured for use as a breast-milk substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.” The product for young children definition includes an important footnote that must always be read as part of the definition and acknowledges that many countries regulate these products as breastmilk substitutes: “Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children means a product manufactured for use as a liquid part of the diversified diet of young children.</p> <p>(1) In some countries these products are regulated as breastmilk substitutes.” Based on these definitions and considering that they are also defined as breastmilk substitutes in the International Code of Marketing of Breast-milk Substitutes (1981) (the Code) as confirmed by World Health Assembly Resolution 69.9 (2016), it makes sense that they be included in the same standard as 2 parts. This would also facilitate implementation coherence between the Code, Codex standards and national laws.</p> <p>2. While in some cases infant formula is necessary, both follow-up formula for older infants and products for young children are not necessary as confirmed by the World Health Assembly in WHA 39.28, “The practice being introduced in some countries of providing infants with specially formulated milks (so-called follow-up milks) is not necessary”, and the WHA 69.9-related Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children has now clarified that these products are all breast-milk substitutes. There is merit, in order to avoid</p>	<p>HKI</p>

<p>any confusion, in distinguishing the sometimes-necessary products (infant formula), which have their own standard, from the unnecessary products (follow-up formula for older infants and products for young children), which should have their own standard.</p> <p>3. Dividing a single standard of conceptually similar products into two parts, based on age-related compositional difference, makes logical sense and the precedent has been set in the Infant Formula Standard (CODEX STAN 72-1981) which has been divided into two parts, Section A: Standard for infant formula, and Section B: Formula for special medical purposes intended for infants. Despite these two products being intended for distinct subsets of infants and having distinctly different composition, they form one standard. The same should apply to the follow-up formula standard with follow-up formula for older infants and products for young children having distinctly different compositions but being conceptually similar and therefore being two sections of the same standard. There is also no justification for separating out the two parts of the standard into two separate standards. Their definition is clear that they are serving the same purpose but for different age groups. And both are a liquid part of the progressively diversified diet. Neither are complementary foods so do not require a separate standard.</p>	
<p>IBFAN is strongly opposed to Option 1.b: This option proposes the creation of two separate standards for Follow-Up Formula and Drinks for Young Children. Both products are recognized as breastmilk substitutes by the International Code of Marketing of Breast-milk Substitutes and World Health Assembly Resolution 69.9 (2016). Separating them into two standards based on age targeting, creates regulatory and consumer confusion and risk both misuse and needless use. IBFAN considers that Option 1.d: one standard, sub-divided into four sections covering Infant Formula, Formulas for Special Medical Purposes, Follow-up Formula and Drinks for Young Children would facilitate more efficient and simplified law-making. As New Zealand has identified in Table 1, numerous provisions are common to ALL FOUR categories. In 2006, CCNFSDU decided to bring Formula for Special Medical Purposes and Infant Formula under one standard precisely because of the similarity of product categories – despite the strong lobby of the baby food industry to have two standards. IBFAN’s second choice is Option 1a. one standard in two parts, covering Follow-up Formula and Part B for Drinks for Young Children. However if this is the preferred option, we advocate that each standard contain a footnote to the title referencing the paired/corresponding/associated Codex standard and recommending that governments address products in both standards in national legislation or regulations so that at national level, all four categories should be covered under one national standard.</p> <p><u>Rationale:</u></p> <p>1. There is no justification for separating the two categories into two separate standards and to do so risks inconsistent and weaker safeguards needed to protect maternal, infant and young child health. Keeping the products under one standard with a clear overarching preamble is essential to safeguard this vulnerable population and ensure appropriate use of all these products.</p> <p>2. As a global recommendation by the World Health Organization breastfeeding for the second year of life is optimal. Hence regardless of how an infant or young child is fed, Follow-Up Formula and Drinks for Young Children, both function – inappropriately – as breastmilk substitutes during the critical time of rapid growth and development when breastfeeding is recommended.</p> <p>3. IBFAN notes that the product definitions in the draft revised standard for both categories serve the same purpose, albeit for different age groups. o Follow-Up Formula is defined as a breastmilk substitute: “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.” o Drinks for Young Children is defined as a “product manufactured for use as a liquid part of the diversified diet of young children” with an important footnote that acknowledges that many countries regulate these products as breastmilk substitutes. ”In some countries these products are regulated as breast-milk substitutes”, as advised by the World Health Organization.</p> <p>4. The International Code of Marketing of Breast-milk Substitutes (1981) and World Health Assembly Resolution 69.9 (2016) are clear that both product categories function as breastmilk substitutes and no distinction is made between them. Recommendation 2 of World Health Assembly 69.9 Guidance on ending the inappropriate promotion of foods for infants and young children “ states “...It should be clear that the implementation of the International</p>	<p>IBFAN</p>

<p>Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products” [milks specifically marketed for feeding infants and young children up to the age of 3 years or older].</p> <p>5. Making further distinctions between these two categories of product would confuse legislators and end users about the roles they play in infant and young child diets. One standard with four parts would better facilitate policy coherence between the International Code of Marketing of Breast-milk Substitutes and World Health Assembly Resolutions, Codex standards and national laws.</p> <p>6. World Health Assembly 39.28 categorically states that these products are not necessary, therefore to give them separate standard status is redundant and gives the impression that they are needed products or that so-called “Drinks for Young Children” are not breastmilk substitutes and, for unstated reasons, exempt from restrictions applicable to breastmilk substitutes, or that they are risk-free.</p>	
<p>IFT Prefers one standard for the reason of demonstrating the changing nutritional needs of older infants as they develop into young children. This demonstration is provided by the point of differentiation at 12 months within one continuous document. The continuity provided by one standard in conjunction with a preamble with a primary objective of providing guidance on relationship of these products to breast milk and possible policy development.</p> <p>b. Two separate standards is not preferred because they would dilute the potential understanding of the changing nutritional needs of older infants as their diets change to those of young children. We agree with the comments against shown in Table 1.</p> <p>c. Noting the above preferences, we could support either approach, but if two separate standards are created, there would be little need for a preamble, particularly for the product for young children, as it bears little resemblance to breast milk and would be difficult to confuse.</p> <p>d. No suggestion</p>	IFT
<p>After careful consideration of the CCNFSDU42 outcomes and taking into account that the Standard is almost finalized, ISDI supports option a) One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children as a more pragmatic way forward. This option is in line with the way the Standard had been developed and elaborated with a clear distinction between the two products emphasized by the clear separation between part A and part B. ISDI also notes that the current format establishes numerous cross references between parts A and B and that having both parts under one Standard facilitates the reading of the respective requirements. From a procedural point of view, ISDI also notes that option a) meets the terms of reference agreed by the CAC36 regarding this work.</p>	ISDI
<p>UNICEF supports option (a) – one standard with two parts for the following reasons:</p> <p>1. Both products are recognized and used as breastmilk substitutes. The current standard contains reference to both products being breastmilk substitutes and their use as a liquid part of the diversified diet. Both products are also defined as breastmilk substitutes in the International Code of Marketing of Breast-milk Substitutes (1981) (the Code) as confirmed by World Health Assembly Resolution 69.9 (2016). As no distinction is made between the products in the Code, no such distinctions are likely to be made by Member States implementing the Code and subsequent WHA resolutions into national laws and regulations. One standard with two parts would facilitate implementation coherence between the Code, Codex standards and national laws.</p> <p>2. While infant formula is sometimes necessary, both follow-up formulas and milk products for young children have been deemed unnecessary by the World Health Assembly (WHA 39.82). Making further distinctions between these two products by having them in separate standards may cause further confusion about the roles they play in infant and young child diets.</p>	UNICEF

3. The STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72 – 1981 sets a precedent of a standard addressing two conceptually similar products (that may be necessary for infants who are not breastfed). It follows that these two products (that are not necessary) also be contained within one standard divided into relevant parts.	
Do you have any further comments on the structure?	
No further comments.	Brazil
Burkina Faso has no further comments.	Burkina Faso
Canada has no further comment on the structure.	Canada
No.	Colombia
Costa Rica has no additional comments regarding the structure of the Standard.	Costa Rica
As a second option, a single document containing four sections referring to infant formula, formula for special diets for infants, follow-up formula for older infants and the product for young children would be considered appropriate, stating “It should be made clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant health standards and Assembly resolutions cover all these products”.	Ecuador
We have no further comments.	Guatemala
Indonesia has no further comments on the structure.	Indonesia
Mali has no further comments.	Mali
Nepal does not have any further comment on the structure.	Nepal
Given that all other aspects of the standard have been finalised, New Zealand considers it is essential to come to an agreement on the structure and preamble so that CCNFSDU (following its 2023 meeting) can forward the Standard to the Commission for adoption and then publication. New Zealand is keen for Member Countries to be able to start using the standard as soon as possible, and we do not want any further delays. New Zealand does not support opening up a discussion on alternative approaches given the work of the 2018 eWG where alternative options were considered but only supported by a few participants. Amongst eWG members there was strong support for limiting structure options to only a) and b) as presented in this CL.	New Zealand
No comments.	Niger
Nigeria has no further comments on the structure at this time	Nigeria
Taking into account that the nutritional requirements of the two groups are different, the food products intended for each of these groups should be substantially different, with their own standards.	Paraguay
None.	Peru
We subscribe to the view that the Follow-up Formula for Older Infants and Product for Young Children are conceptually similar in that they are liquid part of the diversified diet of older infants and young children during the complementary feeding period. These products are both considered to be de	Philippines

facto breast milk substitutes by the International Code of Marketing of Breast-milk Substitutes and the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (4,5). Both products have been agreed to be not nutritionally necessary when a proper and balanced diet is being consumed.	
We have no further comments on the structure.	Thailand
No further comments	Uganda
The UK has no further comments on the structure.	United Kingdom
We have no other observations.	Uruguay
The United States notes that if the Committee chooses to retain the current structure (Option A), then the title of the Codex Standard for FUF (CXS 156-1987) will need to be amended to reflect that product of Part A is the amended standard for FUF and the product of Part B a new product which we have named drink/product for young children. The Committee took a clear decision to not refer to the product of part B using the term "formula". The United States suggests the following title for consideration: Codex Standard for Follow-Up Formula for Older Infants and Drink/Product for Young Children. If the Committee is not willing to change the name of the Codex Standard for FUF (CXS 156-1987), then the United States is of the view that we must choose Option B - Two separate standards or our suggestion above as Option D - Support a different structure approach.	USA
No.	Consumers International
Helen Keller International has no further comments on the structure.	HKI
ISDI has no further comments.	ISDI
PREAMBLE	
Do you think this Standard(s) requires a Preamble? Yes/No. If yes, what is the purpose of having a Preamble for this Standard(s)? Please provide rationale and justification for your thinking (either Yes or No).	
-Australia is of the view a preamble is not required for the Standard(s). Based on NFSDU/42 CRD2 we believe the concepts and guidance from WHO and WHA documents have been incorporated where relevant into the draft standard. We also note the CCEXEC75 advice in regard to references to WHO/WHA documents and that CRD2 shows how this advice has been followed. However a preamble similar to the Infant formula Standard could be included (if the structure is agreed as one standard with two parts) by adopting the last paragraph of the draft preamble (from Recommendation 9 as per CX/NFSDU 17/39/4) with amendments to incorporate the name of the drink/product for young children.'This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)'. Yes. Brazil highlights the importance of including a Preamble in this Standard for both Parts A and B.	Australia
	Brazil

<p>Recently, WHO published a report which summarizes the findings of a multicountry study examining the impact of breastmilk marketing on infant feeding decisions and practices. It exposes the aggressive marketing practices used by the formula milk industry, highlights the impacts on women and families, and outlines opportunities for action (WHO. How the marketing of formula milk influences our decisions on infant feeding. 2022).</p> <p>The main purpose of the International Code of Marketing of Breast-milk Substitute (1981) and WHO guidelines and policies is to protect breastfeeding from the influences of inappropriate marketing of breast-milk substitutes, which includes Follow-up Formula for Older Infants and Product for Young Children.</p> <p>Thus, the current scenario emphasizes the need to explicitly include references to relevant WHO documents and WHA resolutions in a Preamble.</p>	
<p>Burkina Faso believes that a preamble is necessary because it will help the member states to put the standard into context. This is particularly important when considering products intended for a vulnerable age group where clarity is essential for the regulators. The preamble will play an important role in helping to ensure that policies are consistent and in specifying which relevant instruments and international standards concerning infant formulas should be taken into consideration when applying this standard on an international level. The Committee has already recognised the necessity of protecting, promoting and supporting breastfeeding as the best means of providing the ideal diet for healthy growth and development in infants and young children, and a preamble is necessary for this purpose.</p>	Burkina Faso
<p>CAMBODIA strongly believes this Standard requires a Preamble. A preamble will assist Member States to contextualize the standard within existing international instruments, primarily the Code and subsequent WHA resolutions. Both the Code and subsequent WHA resolutions include both follow-up formula and products for young children (all defined as breastmilk substitutes) in the scope, definitions and content. These inform Member States' implementation of the Code into national laws. The preamble can play an important role in helping ensure policy coherence by specifying which relevant international instruments and standards addressing formula milk products are to be considered when applying this standard.</p>	Cambodia
<p>Canada does not think that a preamble is necessary, especially if option b above is chosen since both would be stand-alone standards. Furthermore, as per the Codex procedural manual, a preamble is not required. Finally, Canada does not think that a preamble is necessary given that many of the elements of the WHO Code and the WHA resolutions are already presented within the standard.</p>	Canada
<p>Yes, we think it needs a preamble.</p> <p>The debate on this standard has been lengthy and has provoked a number of differences among members, particularly in the Preamble section. This discussion highlights the discordance or lack of consensus and possible confusion among Member States regarding the context and implications of applying the standard. Precisely because of this situation, the inclusion of a corrected preamble could facilitate the application of the standard, stating in general terms the principles taken into account for the review of the standard, and serving as a context for understanding the intended use of the standard, the need for the standard, and for better understanding and use by Member States. In addition, there is now more knowledge and experience to work out how best to include this type of information in the standard, so that the concerns previously raised about the text could be better addressed.</p> <p>In 2018, the Executive Committee, at its 75th Session, provided guidance on references to WHO/WHA documents in the draft Standard for Follow-up Formula, including:</p> <ol style="list-style-type: none"> a. the references should be considered on a case-by-case basis; and b. the references may provide context and additional information in order to assist members in understanding and using the standards; c. concepts and technical information could be incorporated into the text of the standard itself, instead of referencing sources external to the Codex; 	Chile

<p>d. the references had to be relevant to the scope of the standard itself, fall within the mandate of the Codex, have a scientific basis, and have been developed through a transparent process.</p> <p>We therefore agree with the inclusion of a preamble for this purpose, using the references correctly, and following the recommendations of the CCEXEC, for these purposes.</p>	
<p>Yes, we believe it is appropriate for the standard to include a preamble.</p> <p>Provide a general background to the document and indicate that the standard is divided into two sections: part A for follow-up formula for older infants and part B for the product for young children.</p> <p>The purpose of having a preamble is to provide greater clarity to the reader of the standard and to avoid confusion related to the two types of products covered in the document.</p>	Colombia
<p>Costa Rica does not consider it necessary to include a preamble to the Standard; however, if one is defined, it supports that it should be a simple text that does not affect the approval of the reviewed Standard, given the time it has taken to complete the work.</p> <p><u>Justification:</u> The current Standard for Follow-up Formula does not include a preamble and the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants includes a simple statement of the fact that the Standard is divided into two sections.</p> <p>In addition, the reviewed standard sets out the product definitions, labelling and compositional requirements in detail and, therefore, no additional text or duplicate information should be placed in a preamble.</p>	Costa Rica
<p>Our view is that these standards should not have a preamble: The purpose of the standards is clear and the content thereof is sufficient.</p>	Cuba
<p>Yes.</p> <p>On the basis of the Principle of the Best Interest of the Child, which was established in the framework of the International Convention on the Rights of the Child, Ecuador firmly states that the preamble should serve to clarify to Member States that in the treatment of their laws and regulations, the absolute priority of promoting, protecting and supporting breastfeeding, as well as other natural and minimally processed foods that should be incorporated into the diet of infants and young children, should be applied.</p> <p>Policies must be aligned with the World Health Organisation and World Health Assembly Resolutions on breastfeeding and the prevention of inappropriate promotion of foods for infants and young children.</p>	Ecuador
<p>Egypt is of the opinion that the Standard requires a preamble.</p>	Egypt
<p>The EU is not opposed to have a preamble if there is a support for it in the Committee.</p>	European Union
<p>Guatemala mentions that the standard does not require a preamble; it should be noted that the Codex Procedural Manual describes how Codex standards should be drafted and the sections they should include. According to the Manual (page 55, Codex Procedural Manual, 27th Edition), commodity standards should have the following structure:</p> <ul style="list-style-type: none"> • Name of the Standard • Scope • Description 	Guatemala

<ul style="list-style-type: none"> • Essential Composition and Quality Factors • Food Additives • Contaminants • Hygiene • Weights and Measures • Labelling • Methods of Analysis and Sampling <p>According to the Manual, the structure of Codex commodity standards contained in the Procedural Manual does not require a Preamble section. We note that the current Standard for Follow-up Formula does not include a preamble. In addition, the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants includes a simple statement of the fact that the Standard is divided into two sections.</p> <p>In addition, it is important to stress that the standard has already set out and reviewed the product definitions, labelling and compositional requirements in detail and therefore no additional text or duplicate information should be placed in a preamble.</p>	
<p>In line with comment on supporting the establishment of two separate standards, Indonesia consider that the standards do not require Preamble.</p> <p><u>Rationale:</u> The Format for Codex Commodity Standards contained within the Procedural Manual does not require a preamble section therefore most Codex commodity standards do not contain preamble section. However, in cases such as Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981) in which standard established for two different products, the preamble may contain brief description that the standard covers both infant formula and formulas for special medical purposes intended for infants.</p>	Indonesia
<p>Yes</p>	Iran
<p>Kenya has no strong position on having or not having a preamble to the standard (s).</p> <p><u>Justification</u></p> <p>The decision on whether or not the standard requires a preamble will be appropriately answered by the content of the preamble. In our view, the contents of the body of the standards (both part A and B) has captured the relevant provisions of the International Code of marketing of breastmilk substitutes relevant for the products as guided by CCEXEC75. We will not object to a preamble that would just set the scene of the standard as guided by the chair and as done in CXS 72:1981, standard for infant formula and formulas for special medical purposes intended for infants. Considering the significant work that has already been done on the standard, we are of the opinion that a preamble should not hold the draft standard any further and should there be a stalemate either in content of the preamble or the existence or non-existence of the preamble, we will support progressing the standard without the preamble.</p>	Kenya
<p>Mali believes that a preamble is necessary because it will help the member states to put the standard into context. This is particularly important when considering products intended for a vulnerable age group where clarity is essential for the regulators. The preamble will play an important role in helping to ensure that policies are consistent and in specifying which relevant instruments and international standards concerning infant formulas should be taken into consideration when applying this standard on an international level. The Committee has already recognised the necessity of protecting, promoting and supporting breastfeeding as the best means of providing the ideal diet for healthy growth and development in infants and young children, and a preamble is necessary for this purpose.</p>	Mali
<p>Yes.</p>	Morocco

<p>The preamble forms an integral part of the Codex standards and represents the integrity of the standards' content. It provides general context and includes references for this/these standard(s).</p> <p>Morocco agrees with what was said by the president in reference to RUTF (ready-to-use therapeutic food). The preamble should establish the framework by explaining the general context behind the formulation of these standards.</p>	
<p>Yes, Nepal thinks that a Preamble is required.</p> <p>Considering the importance of the standard to the most vulnerable age group, preamble will be important for Nepal and other member states to ensure coherent policy within existing international standards, particularly the Code and its subsequent WHA resolutions. It will guide member states with relevant global standards or instruments to consider when developing their own national standard.</p>	Nepal
<p>Yes</p>	New Zealand
<p>Niger agrees that a preamble is necessary because it will help the member states to put the standard into context. It is particularly important when considering products intended for a vulnerable age group. The preamble will play an important role in helping to ensure that policies are consistent and in specifying which relevant instruments and international standards concerning infant formulas should be taken into consideration when applying this standard on an international level.</p>	Niger
<p>Yes, Nigeria is of the opinion that the Standard requires a Preamble.</p> <p>Nigeria believes that a Preamble would serve the purpose of setting the tone and the context of the Standard. It will assist Member States, particularly regulators, to contextualize the Standard within existing international instruments, essentially the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions both of which cover follow-up formula and milk products. Having a comprehensive Preamble will provide the necessary clarity for applying the standard, especially for regulators, and will assist countries in effective implementation of the Code and national laws considering the vulnerable age group for whom the products are intended.</p>	Nigeria
<p>Yes</p> <p>We support the view that this standard requires a preamble. A preamble should set the scene by providing the overall context. As both Follow-up Formula for older infants and Product for Young Children are recognized and used as breastmilk substitutes, the overall context in this case should be the protection of breastfeeding, by referring to WHA resolutions and WHO documents that are relevant in the regulation of marketing of breast milk substitutes and protection of breastfeeding. The Codex Alimentarius Commission acknowledges breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. The preamble will provide guidance for Member States to contextualize the standard within existing international instruments and ensure policy coherence by specifying which relevant international instruments and standards must be considered when applying this standard at the national level.</p>	Norway
<p>These standards should have a preamble.</p> <p>Bearing in mind that our approach is to have two separate standards, having a preamble for each standard would provide guidance on the purpose of both standards and avoid confusion when they are applied.</p>	Paraguay
<p>No.</p> <p>The Procedural Manual of the CODEX Alimentarius Commission indicates the format to be followed for CODEX COMMODITY STANDARDS, the structure of which should be as follows:</p> <ul style="list-style-type: none"> ● Title of the Standard 	Peru

<ul style="list-style-type: none"> ● Scope of Application ● Description ● Essential Composition and Quality Factors ● Food Additives ● Contaminants ● Hygiene ● Weights and Measures ● Labelling ● Methods of Analysis and Sampling <p>In this sense, the preamble section is not part of this type of standard and we therefore consider that, in the interest of following the structure for standardisation, a preamble should not be included.</p>	
<p>Yes. We strongly believe that this Standard(s) requires a Preamble as it sets the tone of the over-all context of the Standard.</p> <p>The Preamble sets the framework for the Standard(s) and how it will be used. It will take into account the appropriate use of the Follow Up Formula for Older Infants and Product for Young Children. It sets the stage for the revised Standard(s). It helps in understanding the collective intention of the Committee and the purpose of the Standard(s)</p> <p>The Preamble will play an important role in helping to ensure policy coherence by specifying which relevant international instruments and standards addressing concerns on formula milk products are to be considered in the implementation of this Standard(s) at the national/regional level. Considering that this Standard(s) is intended for the most vulnerable age groups, the Preamble will provide clarity to national/regional regulators on how to use this Codex Standard(s).</p> <p>There were precedents in Codex to include WHA resolutions and WHO guidelines. The Guidelines on Formulated Complementary Foods (CXG 8-1991 Rev. 2013) and Standard for Cereal-Based Foods (CXS 74-1981, Rev. 1-2006) made reference to the Global Strategy for Infants and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001) in the use of such guidelines and standard, respectively (1,2,5).</p> <p>This was explicitly stated in REP19NFSDU paragraph 39 to wit, “the Committee clarified that concerns on the WHO International Code of Marketing of Breast-milk Substitutes, the Global Strategy for Infant and Young Child Feeding and relevant WHA resolutions could be addressed, if not in the scope, through the provisions in the labelling section and in the future discussion on the preamble” (8).</p>	Philippines
<p>ROK reviewed CCFSDU42/CRD2. CCEXEC75 advised (also reassured in CCEXEC77) the WHO/WHA reference used in the draft of the follow-up formular: where it says reference should be reviewed case by case, reference may provide context and additional information to assist the members in understanding and using standards and specifications. Also, it advises that the concepts and technical information can be incorporated into the wording of the standard itself, rather than referencing sources other than the codex to a footnote.</p> <p>According to REP19/NFSDU para 30 and para 45, the committee is concerned about how the WHO international code of marketing of breastmilk substitutes, the Global Strategy for Infant and Young children feeding, and relevant WHA resolutions would be addressed. When the Committee worked on the revision of a CXS 156-1987, incorporating the context into the specific section was a big part of the discussion. NFSDU42/CRD2, Table 1, in particular, shows how the contexts of WHO's 'international code of marketing of breast milk substitutes' and 'guidance on ending the inappropriate promotion of foods for infants and young children' were incorporated well into the revision draft of CXS 156-1987.</p> <p>Text for follow-up formular for older infants has been agreed on by the committee, endorsed by CCFL45, adopted by CAC42, and is held at Step 7. Text for drink/product for Young Children with added nutrients, drink/product for Young Children has been adopted by CAC43, endorsed by</p>	Republic of Korea

CCFL46(REP21/FL, para 24-31), and is up for discussion at step 7. The Committee is almost done with the revision process of the standard. The work of bringing back the contents already included in each provision into the Preamble is meaningless at this point.	
Yes, the Kingdom of Saudi Arabia supports that this standard contains a full preamble, and believes that a well-defined preamble is essential.	Saudi Arabia
Senegal agrees that a preamble is necessary because it will help the member states to put the standard into context. This is particularly important when considering products intended for a vulnerable age group where clarity is essential for the regulators. The preamble plays an important role in helping to ensure that policies are consistent.	Senegal
For Switzerland, the need for a preamble depends on the content of the standard. If the standard contains two product categories it would be desirable to define a short preamble comparable to that of the Infant formula standard; if the standard contains only one product category (follow up formula and products for young children are two independent standards), then a preamble is, in our opinion, not necessary.	Switzerland
<p>We take the view that the Standard(s) does not require a Preamble because:</p> <ul style="list-style-type: none"> - According to the CCEXEC75's advice, concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex. - The table contained in NFSDU/42 CRD 2 illustrates that the EWG and CCNFSDU have followed the advice of CCEXEC75. - Some of the WHA resolutions went beyond the mandate of Codex and therefore were inappropriate to reference. - The format for Codex Commodity Standards contained within the Procedural Manual does not require a Preamble section. 	Thailand
<p>YES.</p> <p><u>Justification:</u> To provide clarity to the standards users, especially noting that these products are both breastmilk substitutes and thus to maximally encourage the act of direct breastfeeding by the mothers up to the recommended age in the preamble.</p>	Uganda
<p>No.</p> <p>Overall, the UK is of the view that the standard(s) for follow-up formula does not require the addition of a Preamble, as the remaining text includes the specific details on the requirements for follow-up formula. The UK understands and supports the views of the committee on the benefits of including a Preamble and if the addition of a Preamble was agreed, then the UK would be content on the basis its inclusion was not in conflict with the remaining requirements of the Standards and it was aligned with the Preamble for the Infant Formula Standard, and Formulas for Special Medical Purposes Intended for Infants standards where the Preamble explains that the Standard is divided into one standard with two parts or Two separate standards, as appropriate and includes a reference that the standards take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001)."</p>	United Kingdom
<p>Yes. Uruguay supports and considers relevant the inclusion of a Preamble covering parts A and B of this Standard, as it will help to contextualise the scope of application of the Standard.</p> <p>The inclusion of a Preamble was proposed following consultation with the Codex Secretariat and the WHO to find a workable solution and to advance the discussion of the standard. At that time it was proposed that a Preamble could include references to relevant documents and/or resolutions, which would replace the need to list or refer to specific documents or resolutions within different sections of the Standard itself, as the Preamble applies to the</p>	Uruguay

<p>Standard as a whole. Therefore, given that this was an option supported by the Codex Secretariat and the WHO and that it was suggested as a solution to the controversy, Uruguay understands that the Preamble should remain in the standard for the purpose for which it was initially defined.</p>	
<p>Yes.</p> <p>If the Committee agrees to maintain the current structure of the proposed draft standard comprising Part A (FUF for Older Infants) and Part B (Drink/Product for Young Children), then the United States feels that a preamble would be helpful to clarify for the reader the differences between the two parts of the standard. This would be a similar approach to that taken by the Infant Formula Standard (CXS 72-1981).</p> <p>In the event the Committee chooses to create two separate standards (one standard for Part A and one standard for Part B), then the United States does not believe it is necessary for each of these two independent standards to have its own preamble. Furthermore, the United States notes that preambles are not required by the Format for Codex Commodity Standards guidance which can be found in the Codex Procedural Manual (see page 55 of the 27th ed.). The United States notes that many, if not most, of the Codex standards established by CCFSDU do not have preambles. It is our view that the Scope and Definition sections of the draft standards (FUF for Older Infants and Drink/Product for Young Children) provide sufficient information so the reader can understand the nature and how to use the standard, making a preamble unnecessary.</p>	<p>USA</p>
<p>Vietnam is of the opinion that This standard does not require a Preamble.</p> <p><u>Rationale:</u></p> <ul style="list-style-type: none"> - According to the Codex Procedural Manual , the commodity standards shall have the following structure: • Name of the Standard • Scope • Description • Essential Composition and Quality Factors • Food Additives • Contaminants • Hygiene • Weights and Measures • Labelling • Methods of Analysis and Sampling <p>According to the Manual, the structure for Codex Commodity Standards contained within the Procedural Manual does not require a Preamble section.</p> <p>Inclusion of Preamble in Codex Standard for commodity will make the different understanding when applying the standard by countries, so creating unnecessary trade barriers.</p>	<p>Vietnam</p>
<p>We are asked to indicate whether we consider that a preamble is necessary and, if yes, which should be its content.</p> <p>EFLA considers that, should option 1 be retained for the structure (one standard in two parts), a short and purely factual preamble should indicate very clearly that the standard contains two parts concerning two different products destined to two different age groups, and that references to the standard should always specify which part is concerned. No other consideration should appear in the preamble (see below comments regarding the hypothesis of option 2)</p> <p>EFLA having explained in point 1. (structure) that it favours option 2, i.e. two separate standards, it considers that, in that case, there should be no preamble in either standard.</p>	<p>AEDA-EFLA</p>

<p>The reasons for this position, based on legal considerations, are the following:</p> <ul style="list-style-type: none"> - The "FORMAT FOR CODEX COMMODITY STANDARDS" provided in the Codex Procedural Manual (Section II: Elaboration of Codex texts) lists the different sections of a standard, among which there is no preamble. Moreover, whereas it is specified that "The sections of the Format require to be completed in a standard only insofar as such provisions are appropriate to an international standard for the food in question", in contrast, no additional section (such as a preamble) is provided for. - Therefore, deviating from this format could constitute an inappropriate precedent that may render standards less clear. Indeed, it derives from the very existence of a format in the Procedural Manual that for standards destined to be read and applied at international level in various legal frameworks, a clear and objective format is necessary. - For example, in some legal environments such as the European Union, regulations and Directives are introduced by the indication of the legal basis and an explanation of the motives which help understand the rationale for the rules laid down by the substantive text. The specific legal significance of these motives has been clarified by the European Court of Justice. Nothing of that sort exists for Codex rules, which are destined to be inserted in various member States having different legal frameworks. The legal value and significance of a preamble describing "the context" of a standard, as suggested in the document, could be interpreted differently among the member States and all stakeholders having to refer to said standard, at the prejudice of its uniform interpretation. This would defeat the purpose of facilitating trade, something which is all the more important since Codex standards are accepted as references for the SPS and the TBT agreements. - In any case, for this standard as well as for any other Codex standard, the context of its adoption could always be found in the minutes of the discussions having led to its adoption. Inserting this context in a preamble would not bring any new information. - Finally, EFLA recalls that Codex standards are not destined to constitute the sole rules and regulations adopted by the member States who adopt them. Those who also wish to refer to the WHO guidelines and WHA resolutions which have been proposed to be introduced in a preamble of the Standard will remain totally free to do so in their own legislation. 	
<p>Yes, we strongly believe this standard requires a preamble.</p> <p>A preamble is very important for this standard because it will reiterate that follow up formulas and drinks are not necessary in the diet and should not be promoted, as stated by WHO. The preamble is also key to help Member States implement these standards at the national level and to make clear that national laws should incorporate the International Code of Marketing of Breast-milk Substitutes and subsequent WHA resolutions into their national legislation. The preamble should mention the key WHO and WHA documents related to this standard. The mentioning of WHO and WHA recommendations in the preamble is key to ensure policy coherence between the Codex standards and existing public health recommendations.</p>	Consumers International
<p>YES it needs a preamble !</p>	ENCA
<p>Helen Keller International believes that a Preamble is required as it will assist Member States to contextualize the standard. This is especially important when considering products for this most vulnerable age group where clarity is essential for regulators. The Preamble will play an important role in helping ensure policy coherence by specifying which relevant international instruments and standards addressing formula milk products are to be considered when applying this standard at the national level. The Committee has already acknowledged the need to protect, promote and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants and young children and to carry this through a Preamble is required.</p>	HKI
<p>The preamble is essential to assist Member States in understanding where these older infant and young child products 'fit' in the national regulatory context. In order to make certain the Codex mandate of protecting consumer health is realized, the preamble can inform the Member States to the need</p>	IBFAN

to include international instruments, primarily the International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly Resolutions, into their national laws.

The preamble can play an important role in helping ensure policy coherence between Codex and the World Health Organization recommendations and World Health Assembly outcomes. This can provide the essential safeguards to protect maternal and child health. It can inform governments about the unique infant and young child nutritional and immunological contributions provided by breastfeeding and the serious long-term risks of these sweetened, highly processed products. Follow-up Formulas and Drinks for Young Children are not like other food products. These follow-up formula products are marketed for use by older infants and young children at their critical stage of their growth and development. A considerable body of scientific peer-reviewed literature documents the health and nutrition risks. This evidence has informed the global consensus that the marketing and promotion of these products must be in full compliance with the International Code of Marketing Breast-milk Substitutes and World Health Assembly Resolutions in order to safeguard the health of children at these vulnerable stages of life. Follow-up Formula and Drinks for Young Children are not necessary as confirmed by the World Health Assembly in WHA 39.28, "The practice being introduced in some countries of providing infants with specially formulated milks (so-called follow-up milks) is not necessary." Energy and nutrient dense family foods and cow's milk can provide the essential complementary foods to meet energy and nutrient requirements for older infants and young children.

Proposed Preamble The Codex Alimentarius Commission acknowledges the need to protect breastfeeding as a vastly safer and nutritionally superior way of providing optimal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for breastfeeding in meeting the nutritional requirements of infants, provided, they are prepared under hygienic conditions; given in adequate amounts; refraining from advertising and claims; and ensuring labels contain prominent, recommended warnings of health risks and hazards of replacing breastfeeding and improper use of substitutes. Preparation instructions must be in applicable local languages. In addition, various products have also been produced intended specifically for older infants and young children as they progress to a more diversified diet of nutrient and energy-dense family foods. These products are not necessary as determined by Member States (World Health Assembly 39.28) and should not undermine breastfeeding. The production, distribution, marketing, sale and use of follow-up formula for older infants and drinks for young children should be consistent with national health and nutrition policies. and be in conformity with the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding as well as Relevant WHO guidelines, policies, World Health Assembly Resolutions that have been endorsed and supported by Member States which provide guidance to countries in this context, including urging Member States to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children, including the misleading practice of cross-promotion.

This Standard is divided into four (or two as our less preferred option) sections. Section A refers to Infant Formula, Section B to Formula for Special Medical Purposes, Section C to Follow-up Formula for Older Infants (6 to 12 months of age), and Section D deals with Drinks for Young Children (12 to 36 months of age).

Notes: Milk-related FAQs - What are the benefits of giving human milk to children over 1 year of age? <https://www.firststepsnutrition.org/milks-marketed-for-children> <https://www.firststepsnutrition.org/fag-page> Global recommendations support continued breastfeeding into the second year of life and WHO guidance recommends all infants are breastfed for up to 2 years and beyond (WHO, 2003).

The rationale for encouraging continued consumption of a milk in young children beyond 1 year of age is based on a combination of meeting energy needs (proportionally driven by the fat content), calcium requirements for bone deposition and the other nutrients that mammalian milk provides. However, in contrast to animal milks, breastmilk can offer not only nutritional benefits but significant health benefits to both mother and child. That said, whilst there is no shortage of evidence for the benefits of breastfeeding during the first year of life, there are relatively few studies that attempt to quantify the benefits of breastfeeding children over 1 year of age.

Nevertheless, those that do support the idea that breastfeeding continues to provide nutrition and immunological protection, is beneficial for IQ and subsequent achievement, provides some protection against overweight and obesity later in life, and offers emotional benefits for as long as it continues. Some benefits continue to be felt beyond the period of breastfeeding (Lopez et al, 2021; NHS, 2020, Grummer-Strawn et al, 2004).

Nutrition Breastmilk composition changes over time to meet the needs of the growing child so that whilst the volume consumed may decrease, an appropriate level of nutrients remains present and immunological protection is not compromised (LLL, 2010).

Studies looking at the composition of breastmilk into the second year of lactation have reported a large degree of stability in the macronutrient content with only a small reduction in protein. Mineral elements stay largely stable, although after two years, some studies report a reduction in calcium and zinc content. Four hundred millilitres of mature breastmilk can meet the following percentage of daily nutrient requirements for a 1-2 year old child: 32% energy. 36% protein 58% vitamin A 53% vitamin C Immunological protection. Studies in breastmilk composition in the second year of lactation have reported inconsistent results. Some studies report increasing concentrations of the antimicrobial protein lysozyme (Perrin et al, 2017; Hennart et al, 1991; Prentice et al, 1984). Perrin et al also reported increasing concentrations of immunoglobulin A (IgA) and lactoferrin (Perrin et al, 2017). These breastmilk proteins provide responsive and protective immunity (Breakey et al, 2015) and support the development of a beneficial gut microflora (Mastromarino et al, 2014). The secretion of antimicrobial proteins differs between mothers and this may mask changes over time and may help to explain differences between studies (Perrin et al, 2017; Lewis-Jones et al, 1985).

More consistently, results of a systematic review and meta-analysis indicate that breastfeeding protects against acute otitis media until 2 years of age, and protection is greater for breastfeeding of longer duration (Bowatte et al, 2015). IQ and general ability Research on the relationship between cognitive achievement (i.e. IQ scores and school grades) and breastfeeding has shown the greatest gains for those children breastfed the longest. Some studies show that participants who were breastfed for 12 months or more score higher on IQ and general ability tests than those with shorter durations of breastfeeding (Victora et al, 2015; Lopez et al, 2021).

The positive influence on IQ as a result of breastfeeding may also impact upon long-term earnings and productivity. One large retrospective cohort study reported that participants who were breastfed for 12 months or more had higher IQ scores, more years of education, and higher monthly incomes than did those who were breastfed for less than 1 month (Victora et al, 2015).

Overweight and obesity It is becoming widely accepted that breastfeeding protects against overweight (Victora et al, 2016). Analysis of 2015-2017 surveillance data collected in 22 European countries reported that, compared to children who were breastfed for at least 6 months, the odds of living with obesity were significantly higher among children never breastfed or breastfed for less than 6 months. Several studies have reported that longer durations of breastfeeding are associated with a lower risk of obesity in later life (Qiao et al, 2020; Zheng et al, 2020; Rito et al, 2019; Horta et al, 2015). A dose response relationship between breastfeeding and protection against overweight and obesity has been reported by several studies (Qiao et al, 2020; Grummer-Strawn and Mei, 2004) and those that have included a breastfeeding duration category of 12 months + have reported significant reductions in risk for overweight and obesity in later childhood. When comparing those who were breastfed for at least 12 months with those who were never breastfed, Von Kreis et al reported a 57% reduction in the odds of being overweight in a subset of over 9,300 Bavarian 5- and 6-year-olds (Von Kreis et al, 1999). When comparing those who were breastfed for more than 12 months to those breastfed for less than 6 months, Liese et al reported a 20% reduction in odds of being overweight among children between 9 and 10 years of age (Liese et al, 2001).

A much larger national analysis of longitudinal data drawn from the US Centers for Disease Control and Prevention Pediatric Surveillance System reported a 51% reduced risk of obesity for white non-Hispanic children who were breastfed for more than 12 months compared to those never breastfed (Grummer-Strawn and Mei, 2004).

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<p>IFT supports a NO for a preamble. It seems unlikely that regulators charged with ensuring compositional details of the standard will pay much attention to the preamble as it does not bear directly on their responsibilities for insuring product identity. However, there is merit in the concept that some countries could use the preamble as guidance for formulating policy, if there is no other platform that integrates and presents the information and conclusions found in the four identified document sources for effective delivery to policy makers. Pragmatically, regulating breastfeeding is beyond the scope of Codex and none of the UN bodies (WHO, FAO, WHA) can mandate or regulate the social infrastructure necessary to support breastfeeding from 0-3 years. For these reasons, the suggested content of the preamble seems ineffectual for the goals the proponents have for it.</p>	IFT
<p>ISDI is of the opinion that the Standard does not require a preamble.</p>	ISDI

Rationale

Procedural Manual

Codex Procedural Manual describes the way Codex Commodity Standards should be elaborated and the sections they should include. According to the Manual (1), the commodity standards shall have the following structure:

- Name of the Standard
- Scope
- Description
- Essential Composition and Quality Factors
- Food Additives
- Contaminants
- Hygiene
- Weights and Measures
- Labelling
- Methods of Analysis and Sampling

According to the Manual, the structure for Codex Commodity Standards contained within the Procedural Manual does not require a Preamble section. ISDI notes that the current Standard for Follow-up Formula does not include a preamble. In addition, the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants includes a simple statement about the division of the Standard into two sections. In addition, ISDI notes that the standard already has elaborated and revised the definitions of the product, labelling and compositional requirements in detail and therefore any further text or duplication through a preamble should not be made.

CCEXEC75 Guidance

ISDI would also raise the attention of delegates to the advice and conclusions of CCEXEC75: In June 2018 (2), the Codex Executive Committee (“CCEXEC”) recommended to CCNFSDU that only references consistent with the the mandate of Codex that have scientific relevance should be considered:

- With regard to references to WHO/WHA documents in the draft CCNFSDU text on follow-up formula, CCEXEC75 provided the following advice intended to assist CCNFSDU in moving forward:
 - references should be considered on a case-by-case basis;
 - references may provide context and additional information to assist members in understanding and use of Standards;
 - concepts and technical information could be incorporated into the text of the Standard itself, rather than referencing sources external to Codex; and
 - references must be relevant to the scope of the Standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

CRD2 prepared by the eWG Chair for CCNFSDU42 shows that the principles and concepts of WHO and WHA documents are already reflected in the standard itself, which is consistent with the CCEXEC75 guidance. In addition, it was noted at CCNFSDU39 that “some WHA resolutions went beyond

<p>the mandate of Codex and therefore was inappropriate to reference them”. ISDI’s position is that reference to WHO guidelines, policies and resolutions should not be included in Codex Standards as they risk undermining the role of harmonized Standards in global food regulation.</p> <p>As a matter of international law, WHA resolutions and guidance and the WHO Code do not meet the requirements for an international standard and thus are inappropriate for inclusion or reference in Codex.</p> <p>As required by CCEXEC75 advice “references must be relevant to the scope of the Standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.”</p> <p>Referencing them in an international standard, like Codex Alimentarius, would create the impression that the WHO instruments are legally binding and meet the procedural requirements of Codex. Importantly, Codex and the –legally binding – World Trade Organization (“WTO”) agreements interlock. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”) requires WTO Members to base their SPS measures and product standards under the WTO Agreement on Technical Barriers to Trade (“TBT Agreement”) on “international standards, guidelines or recommendations” (3) and explicitly recognizes Codex in this respect (4). In 2000, the WTO’s TBT Committee adopted Principles for the Development of International Standards, Guides and Recommendations with respect to Articles 2, 5, and Annex 3 of the Agreement (“Principles”), which set out requirements for the development of international standards, Under the Principles, the process for developing an international standard by an international organization must be transparent, objective, impartial, inclusive, and based on science.</p> <p>Allowing non-binding, non-science-based factors to influence Codex standards would call into question the linkage between Codex and the SPS and TBT Agreements. Severing that linkage would undermine the harmonization of food standards, call into question the validity of Codex recommendations and processes, and would have a significant negative impact on Codex and on international trade.</p> <ol style="list-style-type: none"> (1) Page 55, Codex Procedural Manual, Twenty-seventh edition. (2) Paragraph 14, report of CCEXEC75 (3) Article 3.1 of the SPS Agreement. (4) Annex A.3(a) of the SPS Agreement; Articles 2.4 and 2.5 of the TBT Agreement. 	
<p>Yes, UNICEF believes this Standard requires a Preamble. A preamble will assist Member States to contextualize the standard within existing international instruments, primarily the Code and subsequent WHA resolutions. Both the Code and subsequent WHA resolutions include both follow-up formula and products for young children (all defined as breastmilk substitutes) in the scope, definitions and content. These inform Member States’ implementation of the Code into national laws. The preamble can play an important role in helping ensure policy coherence by specifying which relevant international instruments and standards addressing formula milk products are to be considered when applying this standard.</p>	<p>UNICEF</p>
<p>What detail should the Preamble contain? Please provide rationale and justification for your thinking.</p>	
<p>The nutritional requirements of older infant and young children should be met preferably by breast milk and appropriate locally based food. In that sense, the use of formulae for older infant or products for young children should not undermine breastfeeding or preclude the use of locally based foods.</p> <p>Brazil strongly supports that the production, distribution, sale and use of follow-up formula for older infants and product for young children should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding as well as relevant WHO guidelines and policies and WHA resolutions that have been endorsed/supported by member states. Thus, it is important to clearly state this issue in the text.</p>	<p>Brazil</p>

<p>Brazil suggests including explicitly The Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (WHA 69.9) in the preamble.</p> <p>In this matter, it is important to note that the WHA 69.9 and the Code of Marketing of Breast-milk Substitute are complementary documents. So, both are important to end inappropriate promotion of food for infants and young children.</p> <p>Regarding the wording of the text, Brazil suggests the following amendments:</p> <p>"The Codex Alimentarius Commission acknowledges the need to [protect and support] breast-feeding for the first six months of life and sustained breastfeeding to two years or beyond as an unequalled way of providing ideal food for the healthy growth and development of infants. The nutritional requirements of older infant and young children should be met preferably by breastmilk and appropriate locally based food. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary], as a substitute for human milk in meeting the normal nutritional requirements of infants provided, they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not undermine breastfeeding.</p> <p>The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children that have been [endorsed and supported] by member states [shall also] provide guidance to countries in this context.</p> <p>This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).</p>	
<p>Burkina Faso believes that the preamble should specify the key WHO and WHA documents that the member states should take into consideration when applying this standard. These documents will give substance to the text of the standard. This is necessary to enable the Codex Alimentarius to fulfil its (dual) mandate of protecting the health of consumers, while recognising that older infants and young children are particularly vulnerable and acknowledging the support given by the Committee to breastfeeding. Therefore, the preamble should refer to the International Code of Marketing of Breast Milk Substitutes (1981), to the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, to WHA resolutions 39.28 and 69.9 and to all the other relevant WHA resolutions. A specific reference to WHA resolutions 39.28 and 69.9 is necessary because these resolutions explicitly relate to follow-up formulas. The supplementary reference to all the other relevant WHA resolutions is necessary to ensure the future relevance of the text.</p> <p>The Committee has agreed to base this standard on the standard relating to infant formulas and, because the latter standard recognised the International Code of Marketing of Breast Milk Substitutes, this new standard should also recognise the Code and WHA resolution 69.9.</p> <p>Burkina Faso acknowledges the hard work carried out by the Committee in drawing up a preamble for the project to produce guidelines for ready-to-use therapeutic food (RUTF) and believes that the approach taken in drawing up this preamble could be used when writing the text of the preamble for the new standard.</p>	Burkina Faso
<p>The preamble should specify the key WHO and WHA documents that have been adopted by Member States at the global level that should be taken into account in the application of this Standard. At a minimum, these include the International Code of Marketing of Breast-milk Substitutes (1981), the</p>	Cambodia

<p>WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children and relevant World Health Assembly resolutions including WHA 39.28 (1986), WHA 54.2 (2001) and WHA 69.9 (2016). These documents already inform Member States' development and implementation of national laws on formula milk products. As well as specifying the above documents that specifically govern the products covered in this Standard, Cambodia also strongly supports the inclusion of subsequent WHA resolutions concerning infant and young child feeding, as these provide important updates and guidance as new evidence emerges.</p>	
<p>Should option a be chosen for the structure, then Canada proposes that, similar to the Infant Formula Standard, the details of the preamble only focus on explaining that the standard includes two parts.</p>	Canada
<p>It should be straightforward and include information to set the scene by providing the general context, stating the principles taken into account for the review and development of the standard, indicating the structure of the standard and also including a statement on when these products could be considered for use in the feeding of infants and older children, following the example of the statement of principles and guidance for Member States, present in the preambles or equivalent sections of other Codex texts, such as those shown below:</p> <ul style="list-style-type: none"> • CAC/GL 55-2005 on food supplements: "people should be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement", • CAC/GL 9-1987, which has an introduction section equivalent to a preamble states that: "The Principles take into account provisions of the Principles of nutritional risk analysis and guidelines for their implementation in the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), when applicable. The competent national and/or regional authorities may also consult FAO and WHO publications for further guidance on the addition of essential nutrients", • CAC/GL 23-1997 on health claims, which declares among other principles the following: "Health claims should be consistent with national health policy, including nutritional policy, and support such policies where applicable", and also provides guidance to Member States on the following measure "The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities." <p>Moreover, we agree that the preamble of this regulation should not contain any of the aspects or requirements that are in the main body of the text, nor should it address issues that are outside the scope of the Codex.</p>	Chile
<p>This Standard is divided into two parts. Part A refers to follow-up formula for older infants and Part B refers to drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children.</p> <p>This preamble makes it possible to differentiate the two products, which is emphasised in the standard, and also makes it easier to read the respective requirements.</p>	Colombia
<p>If it is agreed to include a preamble, it should make specific reference to the fact that the Standard is divided into two sections, like in the preamble of the Standard for Infant Formula. The text could read as follows:</p> <p>"This Standard is divided into two sections. Section A refers to follow-up formula for older infants and Section B refers to drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children."</p> <p><u>Justification:</u> The current Standard for Follow-up Formula does not include a preamble and the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants includes a simple statement of the fact that the Standard is divided into two sections</p>	Costa Rica

<p>In addition, the reviewed standard sets out the product definitions, labelling and compositional requirements in detail and, therefore, no additional text or duplicate information should be placed in a preamble.</p>	
<p>In line with the Codex Alimentarius mandate to protect the health of consumers, the preamble for this type of product is essential to provide clear information on the following:</p> <ol style="list-style-type: none"> 1.- The importance of breastfeeding for its benefits for the health of the child, the mother, national development and preservation of the environment. 2.- It should be noted that the recommendations of the World Health Assembly state that: "Emphasis should be placed on the use of suitable, nutrient-rich, home-prepared, and locally available foods that are prepared and fed safely". Highlighting that follow-up formulas and drinks for young children are not necessary, as confirmed by World Health Assembly resolution 39.28 of 1986. 3.- It should be noted that formula should only be used when necessary with the advice of a health professional. Therefore, it is suggested to mention (underlined text added), "At the same time, the Codex recognises that numerous formulas have been produced, intended to be used, only when necessary, as a substitute for breast milk to meet the normal nutritional requirements of infants and young children, provided they are prepared under hygienic conditions, given in adequate amounts and only used on the advice of a health professional". 4.- Clarify that the processes of production, distribution, sale and use of follow-up formula for older infants and products for young children should not discourage breastfeeding and should be firmly within the framework of the International Code of Marketing of Breast-milk Substitutes (1981); the Global Strategy for Infant and Young Child Feeding, as well as the World Health Assembly's resolutions on these issues, most notably WHA Resolution 69.9 (2016) and the Guidance on Ending the Inappropriate Promotion of Foods to Infants and Young Children (WHA 69.9), which should also be cited in the preamble. 	Ecuador
<p>Egypt proposes the following preamble:</p> <p>The Codex Alimentarius Commission acknowledges the need to protect and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants provided. The production, distribution, sale and use of follow-up formula for older infants and Product for Young Children should be consistent with national health and nutrition policies and relevant national/regional legislation. This Standard is divided into two parts. Part A covers Follow-up Formula for Older Infants (6 to 12 months of age) and Part B covers Drink/ Product for young children, (12 to 36 months of age), with added nutrients or Drink/ Product for young children.</p>	Egypt
<p>Guatemala indicates that based on the above we support the finalisation of the Standard for Follow-up Formula at CCNFSDU43 (March 2023) and its submission for final adoption at CAC46 (TBC in 2023) after ten years of discussion.</p> <p>In line with the Standard for Infant Formula, the following statement is suggested at the beginning of the Standard for Follow-up Formula to indicate that the Standard contains two sections referring to different age groups:</p> <p>This Standard is divided into two parts. Part A refers to follow-up formula for older infants and Part B refers to drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children.</p>	Guatemala
<p>If the revised standard should be established as one standard with two parts, the preamble should contain brief explanation that standard is divided into two sections, as follows:</p> <p>This Standard is divided into two sections. Part A covers the requirements for Follow-up Formula for Older Infants and Part B covers the requirements for Product for Young Children.</p>	Indonesia

<p><u>Rationale:</u> the proposed text refers to the preamble of Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).</p>	
<p>The Preamble can contain two separate parts</p> <p>In the first part, considering the special importance of infant feeding, the importance and necessity of feeding infants with breast milk should be briefly mentioned, and it should be emphasized that replacing breast milk with Follow-up Formula only in necessary and unavoidable cases due to physiological reasons, mother's illness or It is recommended for any logical reason that it is no longer possible to fully feed the baby with breast milk or that breast milk is not enough to meet the infant's nutritional needs.</p> <p>In the second part, it is necessary to point out the importance of the similarity of follow-up formula compounds to breast milk and emphasize the aspects of proper processing, nutrition and safety to maintain the health of the infant.</p>	Iran
<p>Mali believes that the preamble should specify the key WHO and WHA documents which the member states should take into consideration when applying this standard. These documents will give substance to the text of the standard. This is necessary to enable the Codex Alimentarius to fulfil its (dual) mandate of protecting the health of consumers, while recognising that older infants and young children are particularly vulnerable and acknowledging the support given by the Committee to breastfeeding. Therefore, the preamble should refer to the International Code of Marketing of Breast Milk Substitutes (1981), to the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, to WHA resolutions 39.28 and 69.9 and to all the other relevant WHA resolutions. A specific reference to WHA resolutions 39.28 and 69.9 is necessary because these resolutions explicitly relate to follow-up formulas. The supplementary reference to all the other relevant WHA resolutions is necessary to ensure the future relevance of the text.</p> <p>The Committee has agreed to base this standard on the standard relating to infant formulas and, because the latter standard recognised the International Code of Marketing of Breast Milk Substitutes, this new standard should also recognise the Code and WHA resolution 69.9.</p> <p>Mali acknowledges the hard work carried out by the Committee in drawing up a preamble for the project to produce guidelines for ready-to-use therapeutic food (RUTF) and believes that the approach taken in drawing up this preamble could be used when writing the text of the preamble for the new standard.</p>	Mali
<p>The information that should be included in the preamble consists of the points relating to the scope of the Codex with reference to the general principles of the Codex Alimentarius. The preamble should establish the framework by explaining the general context, but should not specify the product requirements. However, it can provide references to the basic composition of the product and the target age groups, without covering the detailed product requirements in the standards.</p>	Morocco
<p>Nepal believes that the Preamble should contain specific reference to the International Code of Marketing of Breast-milk Substitutes (1981), the WHO guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, WHA resolutions 39.28 and 69.9. These WHO and WHA documents will be important to consider by member states in the application of this standard in their national context to support optimal breastfeeding and protect the health of the vulnerable groups, that is, infant and young children.</p>	Nepal
<p>Given our preference for one standard which covers the two product categories, the purpose of a preamble would be a simple statement which says that the Standard is divided into two sections. The Preamble should contain no more than a simple statement which says that the Standard is divided into two sections. The Preamble should not introduce any new concepts or text that is in conflict with, or more stringent than, the composition and labelling aspects within the Standard as these have already been agreed by the Committee. Further, we do not see a need to duplicate any text or concepts in the preamble that have already been covered within the Standard and that were agreed as a result of significant discussion and compromise within the Committee.</p>	New Zealand

<p>Niger believes that the preamble should specify the key WHO and WHA documents which the member states should take into consideration when applying this standard. These documents will give substance to the text of the standard. This is necessary to enable the Codex Alimentarius to fulfil its dual mandate of protecting the health of consumers, while recognising that older infants and young children are particularly vulnerable and acknowledging the support given by the Committee to breastfeeding.</p> <p>Therefore, the preamble should refer to the International Code of Marketing of Breast Milk Substitutes (1981), to the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, to WHA resolutions 39.28 and 69.9 and to all the other relevant WHA resolutions. A specific reference to WHA resolutions 39.28 and 69.9 is necessary because these resolutions explicitly relate to follow-up formulas. The supplementary reference to all the other relevant WHA resolutions is necessary to ensure the future relevance of the text.</p>	Niger
<p>Nigeria is of the view that the Preamble should contain specific details that will guide the application of the Standard. The Preamble should specify the key documents of the WHO and WHA which have been adopted by Member States at the international level which should be considered in applying the Standard. Nigeria believes that at the minimum the Preamble should refer to the International Code of Marketing of Breast-milk Substitutes (1981), the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children and relevant World Health Assembly resolutions including WHA 39.28 (1986), WHA 54.2 (2001) and WHA 69.9 (2016). These are considered important to be in the Preamble also in fulfilment of the mandate of Codex Alimentarius to protect the health of consumers, especially in recognition of the vulnerability of infants and young children in this case.</p>	Nigeria
<p>The preamble should have reference to the key WHO and WHA documents that should be taken into account in the application of this standard. These should include The International Code of Marketing of Breast-milk Substitutes (1981), WHA 69.9 (2016) with the guidance document "Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children", and other relevant WHA resolutions including WHA 39.28 (1986) and WHA 54.2 (2001). The preamble should include a reference to subsequent WHA resolutions concerning infant and young child feeding, as these provide important updates and guidance as new evidence emerges.</p>	Norway
<p>These preambles should be concise with regard to the purposes of each of these standards.</p>	Paraguay
<p>In line with the previous response, we do not consider a preamble to be relevant. However, we suggest that a statement clarifying the structure of the standard might be included, as follows: "This Standard is divided into two sections. Section A refers to follow-up formula for older infants, and Section B refers to products for young children."</p>	Peru
<p>Most importantly, the Preamble should contain provision indicating protection and support for optimal breastfeeding. We propose retention of the previously proposed section of the Preamble in the EWG: The Codex Alimentarius Commission acknowledges the need to protect and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of older infants and young children. This is necessary to fulfill its mandate of protecting the health of consumers, recognizing that older infants and young children are especially vulnerable. A Preamble is required to carry this through.</p> <p>Consistent with the intent of the EWG Chair who engaged with the Codex Secretariat and WHO to progress this issue and find a workable solution, we strongly support the inclusion of relevant recommendations made in the following documents in the Preamble to protect the practice of breastfeeding (4,6,7):</p> <ul style="list-style-type: none"> <input type="checkbox"/> International Code of Marketing of Breast-milk Substitutes (1981) <input type="checkbox"/> WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children <input type="checkbox"/> WHA 39.28 	Philippines

<p><input type="checkbox"/> WHA 47.5</p> <p><input type="checkbox"/> WHA 55.2</p> <p><input type="checkbox"/> WHA 63.23</p> <p><input type="checkbox"/> WHA 69.9</p> <p>Such referencing are consistent with the advice of the Executive Committee of the Codex Alimentarius Committee during its 75 th Session (REP18/EXEC2-Rev.1) as follows:</p> <p>a. references should be considered on a case-by-case basis;</p> <p>b. references may provide context and additional information to assist members in understanding and use of standards;</p> <p>c. concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex; and</p> <p>d. references must be relevant to the scope of the standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process (9)</p> <p>We are of the opinion that the Committee should take into consideration including such resolutions as these have been supported by Member States to provide guidance to countries in this context. Member States that had adopted the 1981 Code of Marketing of Breastmilk Substitutes have obligation to promote breastfeeding beyond 6 months, and reference to relevant WHO policies could serve as reminder to competent authorities. Conflict of interest safeguards are included in all WHO policies and recommendations, and are highly relevant for the standard-setting procedures of Codex.</p>	
<p>The preamble shall highlights the relevant WHO documents, the Global Strategy on Infant and Young Child Feeding, the International Code of Marketing of Breastmilk Substitutes and relevant WHA resolutions, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children.</p>	<p>Saudi Arabia</p>
<p>Senegal believes that the preamble should specify the key WHO and WHA documents which the member states should take into consideration when applying this standard. These documents will give substance to the text of the standard. The preamble should refer to the International Code of Marketing of Breast Milk Substitutes (1981), to the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, to WHA resolutions 39.28 and 69.9 and to all the other relevant WHA resolutions. We believe that the approach taken by the electronic working group for RUTF in drawing up a preamble for the project to produce guidelines for ready-to-use therapeutic food (RUTF) could be used when writing the text of the preamble for this standard.</p>	<p>Senegal</p>
<p>South Africa is of the opinion that two separate standards do not require a preamble.</p> <p><u>Rationale:</u> Codex Procedural Manual describes the way Codex Commodity Standards should be elaborated and the sections they should include. According to the Manual , the commodity standards shall have the following structure:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Name of the Standard <input type="checkbox"/> Scope <input type="checkbox"/> Description <input type="checkbox"/> Essential Composition and Quality Factors <input type="checkbox"/> Food Additives <input type="checkbox"/> Contaminants <input type="checkbox"/> Hygiene 	<p>South Africa</p>

<p> <input type="checkbox"/> Weights and Measures <input type="checkbox"/> Labelling <input type="checkbox"/> Methods of Analysis and Sampling </p> <p>According to the Manual, the structure for Codex Commodity Standards contained within the Procedural Manual does not require a Preamble section.</p> <p>The current Standard for Follow-up Formula does not include a preamble. In addition, the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants includes a simple statement about the division of the Standard into two sections.</p> <p>Also, the standard already has elaborated and revised the definitions of the product, labelling and compositional requirements in detail and therefore any further text or duplication through a preamble should not be made.</p> <ul style="list-style-type: none"> • To be in line with other relevant standards such as Standard for follow-up formula (CXS 156-1987), standard for canned baby foods (CXS 73-1981), standard for processed cereal-based foods for infants and young children (CXS 74-1981). • If there is to be two separate standards, then we propose that there is a need to include the following statement (1.4) as it appears in the current infant formula standard under the scope of the standard: <p>‘The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001)</p>	
<p>The UK understands and supports the views of the committee on the benefits of including a Preamble and if the addition of a Preamble was agreed, then the UK would be content on the basis its inclusion was not in conflict with the remaining requirements of the Standards and it was aligned with the Preamble for the Infant Formula Standard, and Formulas for Special Medical Purposes Intended for Infants standards where the Preamble explains that the Standard is divided into one standard with two parts or Two separate standards, as appropriate and includes a reference that the standards take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).”</p>	United Kingdom
<p>Scientific evidence shows that Exclusive Breastfeeding during the first six months of life accompanied thereafter by safe and appropriate healthy complementary foods is the best option in terms of health and nutrition for infants and young children. Breastfeeding has short- and long-term health benefits for mother and child, and for this reason it should be protected as an original, culturally and behaviourally based feeding practice, not as something interchangeable with artificial feeding. The use of formula for older infants or products for young children should not undermine the practice of breastfeeding or discourage the use of local foods; therefore, their production, distribution, sale and promotion should take into account the provisions of the International Code of Marketing of Breast-milk Substitutes (1981) and the WHO/AMS resolutions supplementing and extending the Code that have been adopted or supported by Member States. In addition, Uruguay supports the inclusion of an explicit reference to WHA Resolution 69.9 Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children.</p> <p>With regard to the proposed text, Uruguay suggests the following amendments:</p> <p>The Codex Alimentarius Commission confirms the need to protect and support exclusive breastfeeding during the first six months of life accompanied thereafter by safe, harmless and healthy complementary foods as an unparalleled means of providing ideal nourishment for healthy growth and development of infants and young children. At the same time, the Codex recognises that numerous formulas have been produced, intended to be used, where appropriate, as a substitute for human milk to meet the nutritional requirements of infants, provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children, which are suitable for their transition towards a more diversified diet based on home-prepared foods, and these products should not undermine the practice of breastfeeding.</p>	Uruguay

<p>The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions, including WHA resolution 69.9 (2016) and the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children that have been [endorsed/supported] by Member States [may also provide] guidance to countries in this context.</p> <p>This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CXS 72-1981).</p>	
<p>Information to clarify the difference between Part A (FUF for Older Infants) and Part B (Drink/Product for Young Children) of the combined standard is all that would be required in the preamble. This would be consistent with the preamble of the Infant Formula Standard (CXS 72-1981). The preamble need only contain the name and definitions of the products of the two parts of the standard and this text should be taken directly from those sections of the standards. Additional text and/or references are not necessary for the preamble as all critical aspects important to the standard have been thoroughly discussed, agreed to, and incorporated into the text of the standard by the Committee – in particular, the definitions and labeling sections. This is consistent with the guidance provided by CCEXEC75 and reaffirmed by CCEXEC77 (see REP18/EXEC2-Rev.1, paras 12-18 and REP19/EXEC2, para. 11).</p> <p>The United States views Codex standards as important technical documents with the aim of harmonizing definitions, composition, labeling, and/or safety aspects for the products of the standards. The United States views the CCEXEC75 advice provided in REP18/EXEC2-Rev.1 para. 14 to be applicable to all Codex standards, not just the Standard for FUF (CXS 156-1987). Further, the United States believes that references in Codex standards should be use on a limited basis and only used when they provide substantive technical information relevant to any particular standard that cannot be sufficiently captured within the text of the standard.</p> <p>The United States acknowledges that some members of the Committee have expressed the importance of the WHO's International Code of Marketing of Breast-Milk Substitutes ("the WHO Code") and have advocated for including the WHO Code as a reference to a potential preamble.</p> <p>As FUF for Older Infants has been defined in the Definitions section as a breastmilk substitute, the WHO Code would apply to the product of Part A of the standard. Therefore, a reference to the WHO Code is not necessary because it applies to the product according to its definition. Therefore, the United States does not support including WHO references within the preamble of Part A of the standard (FUF for Older Infants).</p> <p>As the Committee could not come to agreement due to opposing views as to whether Drink/Product for Young Children should be considered to be a breastmilk substitute (or not), this determination can then be made through regional or national legislation. Therefore, any reference to the WHO Code in relation to Part B of the standard (Drink/Product for Young Children) is not appropriate.</p>	USA
<p>The preamble should specify that these products are NOT necessary as determined by Member States (World Health Assembly 39.28) and should not undermine breastfeeding. It should also mention that the sale and marketing of these products must be in conformity with the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding as well as Relevant WHO guidelines, policies, and World Health Assembly Resolutions that have been endorsed and supported by Member States and provide guidance to countries on this topic.</p>	Consumers International
<p>A reference to the International Code and all relevant subsequent resolutions for example WHA 39.28 .</p>	ENCA

<p>Helen Keller International believes that the Preamble should specify key WHO and WHA documents that Member States should take into account in the application of this Standard. Both give substance to the text contained in the Standard. This is necessary in order for Codex Alimentarius to carry out its (dual) mandate of protecting the health of consumers, recognizing that older infants and young children are especially vulnerable, and the Committee's stated support of optimal breastfeeding. Thus, reference in the Preamble must be made to the International Code of Marketing of Breast-milk Substitutes (1981), the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, WHA 39.28 and WHA 69.9 as well as making reference to all other relevant WHA resolutions. Specific reference to WHA 39.28 and WHA 69.9 is required as these resolutions deal explicitly with follow-up formula. The additional reference to all other relevant WHA resolutions is necessary to future-proof the text.</p> <p>The Committee agreed to base this Standard on the Infant Formula Standard, and just as that standard has recognized the International Code of Marketing of Breastmilk Substitutes, so too must this Standard recognize both the Code and WHA 69.9.</p> <p>Helen Keller International notes the hard work undertaken by the Committee to develop a Preamble for the Draft Guidelines for Ready to Use Therapeutic Foods (RUTF) and believes that the approach taken to develop that Preamble could be used in drafting Preamble text for this Standard.</p>	HKI
Do not believe a preamble is needed.	IFT
<p>Considering the above-mentioned rationale and the only existing precedent in a Codex commodity Standard (1), ISDI supports the finalization of the Follow Up Formula Standard in CCNFSDU43 (March 2023) and sending it for final adoption at CAC46 (in 2023) after ten years of discussion.</p> <p>(1) Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).</p> <p>Consistent with the Infant Formula standard, ISDI could support the following statement at the beginning of the Follow Up Formula standard:</p> <p>This Standard is divided into two parts. Part A covers Follow-up Formula for Older Infants and Part B covers Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children.</p>	ISDI
<p>The preamble should specify the key WHO and WHA documents that have been adopted by Member States at the global level that should be taken into account in the application of this Standard. At a minimum, these include the International Code of Marketing of Breast-milk Substitutes (1981), the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children and relevant World Health Assembly resolutions including WHA 39.28 (1986), WHA 54.2 (2001) and WHA 69.9 (2016). These documents already inform Member States' development and implementation of national laws on formula milk products. As well as specifying the above documents that specifically govern the products covered in this Standard, UNICEF also strongly supports the inclusion of subsequent WHA resolutions concerning infant and young child feeding, as these provide important updates and guidance as new evidence emerges.</p>	UNICEF