JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Fortieth Session
Berlin, Germany, 26 - 30 November 2018
Review of the Standard for Follow-up Formula: scope, product definition and labelling
Comments at Step 3 in reply to CL 2018/63-NFSDU

Comments of Argentina, Australia, Brazil, Cambodia, Canada, Colombia, Costa Rica, Côte d’Ivoire, Ecuador, Egypt, European Union, Ghana, India, Indonesia, Iran, Jamaica, Malaysia, Mali, Nepal, New Zealand, Norway, Peru, Philippines, Senegal, Sri Lanka, Switzerland, United States of America, Viet Nam, EU Specialty Food Ingredients, HKI, IBFAN, ISDI and UNICEF

Background
1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/63-NFSDU issued in September 2018. 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.
### General Comments

Australia continues to support the general alignment of the labelling of Follow-up Formula (FUF) for older infants with the Infant Formula Standard (CODEX STAN 72-1981) as previously agreed by the Committee. We would also like to reiterate our support for the Committee’s decision that there is a point of differentiation between the two FUF products at 12 months. We consider that [Name of food] for young children has a different role and purpose and is therefore not a breast-milk substitute. This view is supported by the differing compositional requirements between the two FUF products as agreed by the Committee (currently at Step 5). On this basis our response has been designed by this view on the differing role of [Name of food] for young children and we therefore do not in general support alignment of the all of the labelling elements of [Name of food] for young children with FUF for older infants. However in an effort to forge consensus we have sought to limit proposed changes wherever possible.

**Proposed Timeline for Completion of Work**

Australia agrees to the proposed timeline. We support the timely progression of this work, and acknowledge the proposed timeline is dependent on the outcomes of Committee discussions and progress made at CCNFSDU40. We strongly encourage the Committee to progress this work according to this proposed timeline. Australia would like to re-iterate the Chairs comment about progressing the work to enable the timely completion of the Standard(s). We consider that prioritisation of the structure could assist with other outstanding considerations i.e. the Preamble, definitions and labelling.

Brazil agrees with the proposed timeline for completion of work

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Cambodia would like to make it clear that Codex plays a critical role in protecting optimal infant and young child feeding practices. Standards developed by Codex often serve as the basic for national legislation, and as such, have a profound impact on infant and young child nutrition. Yet protecting both consumer health and trade can come into conflict, as is evidence in the current debate regarding this agenda items, the review of the standard for follow-up formula, where trade and commercial interests are clearly taking precedence over health. Codex has the opportunity to protect breastfeeding and improve child nutrition and make major contribution to reducing preventable child deaths. We therefore appeal that at this meeting, the matter be discussed with the focus on protecting consumer health. The world took a bold step towards saving children’s lives at the 2016 World Health Assembly when countries adopted resolution WHA 69.9. Codex should take an equally bold step and define follow-up formula for older infants and young children as breast milk substitutes.

Côte d’Ivoire supports the proposal as formulated.


All products included in this regulation must be defined as breast-milk substitutes and, therefore, must be governed by the International Code of Marketing of Breast-Milk Substitutes.

New Zealand supports the general approach that any requirements for Follow-up formula for older infants and [Name of product] for young children should not be more restrictive than in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (STAN 72-1981).

Furthermore, New Zealand notes developments since CCNFSDU39 that are relevant to this work:
(a) an addendum issued to the report of CCNFSDU39; and  
(b) the CCEXEC at its 75th session provided commentary and guidance in relation to the Follow-up Formula Review.

The opinion of the National Technical Committee on Nutrition and Foods for Special Dietary Uses in the framework of the Codex Alimentarius with respect to the document CL 2018/63/OCS-NFSDU is to be in agreement with the document. However, there are comments as indicated in the specific observations.

The Philippines supports the proposed Draft Revised Standard Standards for Follow Up Formula. This has been consistent with the outcome of the electronic working group and consensus of the previous Committee Session as justified by generally accepted scientific evidence. These are also in line with the previous Philippine Positions.

We note that the Committee has acknowledged that there are different nutritional requirements as well as a different role for follow-up formula in the diets of older infants compared to that of young children (12-36 months of age). Thus, we consider that separate Standards would clearly address these differences and is supported by the nutritional composition that has evolved based on the agreed point of differentiation at 12 months of age.

The older infant (6-12) months of age is still considered and defined by Codex as an “infant.” The older infant is just beginning to consume foods while relying on breastmilk or a breastmilk substitute to address nutritional requirements and in meeting their continuing growth needs. The Follow-up Formula for older infants (FUF-OI) 6-12-month-old is a product that is nutritionally complete and provides a nutritional “safety net” while the infant continues to adapt to and consume a complementary diet. However, the young child of 12 to 36 months of age’s diet is now more diverse and includes an increasing variety of various foods which should be meeting most of the young child’s nutritional needs under normal circumstances. Although the product for the 12-36-month-old age group is not nutritionally complete, the nutritional profile of the product can be adapted to address the nutritional needs based on the types of foods typical in a country or region. The product for the 12-36-month-old is not being designed as a complete source of nutrition and consequently, cannot be considered nutritionally adequate to serve as a breastmilk substitute. A separate Standard for the 12-36-month-old product is needed to assure these products can provide meaningful nutrition within the diverse diet of young children sufficient to assure the nutrient adequacy necessary for healthy growth and development. A separate standard better enables the nutritional composition of the product to be customized to the foods being introduced to these young children. Such a Standard is critical to make certain there are sound international specifications that assure safety, nutritional adequacy, and labelling provisions in support of regional and global trade.

The United States considers completion of the revision of the Follow-up Standard to be a priority for the Committee and considers separate standards as the most efficient approach to enable moving through the Codex approval process to formal adoption and note that there are no procedural implications other than the need to inform CAC.

The United States suggests consideration of clarifying the objective of certain labeling sections to facilitate meaningful translations.

Since the text for the Preamble and the Scope remains indeliced, IBFAN has included the requirement for the provisions of the International Code, the relevant WHA resolutions and the WHA69.9 Guidance to Ending the Inappropriate Marketing of Foods for Infants and Young Children into both the preamble for the proposed standard and the scopes of both sections. IBFAN has retained the text of 1.4 in the scopes of both the section on formula for older infants and for name of the product for young children as it is written in the Standard for Infant Formula and Formulas for Special Medical Purposes, (Codex Stan 71-1981) with a slight modification of “shall conform to”.

IBFAN is also of the opinion that for legal clarity, the labelling provisions for all products labelled as follow-up formula must be aligned - whether for older infants or for young children.

ISDI supports the recommendation of CCEXEC75 to CCNFSDU:

**Conclusion**

With regard to references to WHO/WHACodecs in the draft CCNFSDU text on follow-up formula, CCEXEC75 provided the following advice intended to assist CCNFSDU in moving forward:

- a. references should be considered on a case-by-case basis;
b. references may provide context and additional information to assist members in understanding and use of standards;  
c. concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex; and  
d. references must be relevant to the scope of the standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

**GENERAL COMMENTS**

**PRODUCT NAME FOR YOUNG CHILDREN (RECOMMENDATION 18)**

**Recommendation 18**  
Brazil understands that the proposed name is still generic and does not indicate the true nature of the product. So, considering the General Standard for The Labelling of Prepackaged Foods (CXS 1-1985), we consider that the name must be more specific. In our opinion, a better way to characterize the product is informing the main protein source in the name of the product. In this way, we suggest the following amendments: “Formulated milk-based (or plant-based) drink for young children”. We also note that it is of our acknowledgment that the provision 9.1.3 of Section 9.1 will allow for the name of the product to be further qualified with respect to the protein source as a separate labelling provision. But our proposal is to include this information in the name of the product and, consequently, if it is considered, it will be necessary to change the text of the item 9.1.3 aiming to avoid duplication.

The product Name for young children should not include the word “formula” but rather be called “drink for young children”: The WHO has called these products unnecessary. Therefor, the name used to describe the product for young children shall be neutral and contain no implied benefit/claim. Use of proposed objective “formulated” could be interpreted as indicating a benefit.

The name of the product for young children: Drink [designed] for young children

Cote d’Ivoire does not support this proposal and proposes the name “drink for young children”.

The EU does not support the term “formulated” in the name as it is very similar to “formula” and caregivers may therefore be misled as to the appropriate age group of consumers for this product. Consumers may purchase products checking the product name and information on the front-of the pack and may be confused by the product names “infant formula”, “Follow-up Formula for Older Infants” and “formulated drink for young children”. The EU would like to note that consumers, in particular from lower socio-economic groups, may have difficulty in distinguishing age groups and products mentioned such as “infant”, “older infant” and “young child” and “formula”, “follow-up formula” and “formulated drink”. Therefore, the EU considers that to avoid any misunderstanding, the word “formulated” should be deleted, so that the product name would read: “Drink for young children” or, as another alternative, “Young child drink”.

Nepal strongly opposes the word “formulated” since we believe that there is still considerable discussion to be done at the CCNFSDU meeting. We believe that this must be open for discussion at the upcoming meeting in 2018. Nepal not only believes in generating consensus during the Codex meeting, but also depends significantly on the WHO guidance while formulating national policies.

At the WHA in 2016, Nepal supported that these products are breast-milk substitutes and currently the government is formulating policies that ends the inappropriate promotion of foods for infants and young children as is required of countries by WHA 69.9 that was adopted by consensus. In this regard, we believe that the word “formulated” may be used by the manufacturer to inappropriately market these products as it could be perceived as being beneficial.

The world has agreed that these products are not necessary. We believe in using a more neutral word that does not confuse the consumers who may believe that this is a special kind of milk and should be fed to the children. Besides that, studies have found that “special” wording in the labelling confuses consumers of advanced countries, and hence there are great chances that consumers of countries like Nepal will be highly encouraged to feed this product which would in turn discourages breastfeeding.

Thus we propose that the term “Formulated” should be deleted and the name of the product be “Drink for Young Children”, as...
New Zealand supports the name Formulated drink for young children for product for the 12 – 36 months age group.

Mali is in favour of a single standard divided into two categories: Category: 6-12 months and then Category: 12-36 months.

Senegal does not support this proposal and proposes the name “drink for young children”.

IBFAN notes that the manufacturers of products for young children are labelling these products to avoid the classification of breastmilk substitutes. Products are labelled as “growing up milks”, “nutrition supplements for young children”, or “complementary foods” while labelled and marketed to be used from the age of 12 months. Hence they are marketed to be used as breastmilk substitutes and therefore, as clarified by the WHA69.9 Guidance, must be classified as breastmilk substitutes and must comply with the provisions of the International Code and all the relevant WHA resolutions.

Article 9 of the Code that products do not have any pictures or text that idealize their use;

Recommendation 5 of the Guidance prohibits cross-promotion, (also called brand crossover promotion or brand stretching) through direct or indirect promotion through packaging and labelling.

Although the name of the product has not been fully discussed by the Committee, IBFAN is of the opinion that the WHA69.9 Guidance definition of foods for infants and young children applies to all these products: “foods for infants and young children are defined as commercially produced food or beverage products that are specifically marketed as suitable for feeding children up to 36 months of age.”. Since formula products are not defined as milks from mammary glands, IBFAN rejects the use of the term “milks”. Also processed products designed for young children can be nutritionally risky when fed to infants, we hope that there will be a fruitful, comprehensive discussion during which the most appropriate name and terminology can be found that will reduce the risks of needless and inappropriate use of these products and any nutritionally dangerous spill-over to younger infants. The name of any product that functions as a breastmilk substitute must take into account these risks.

Argentina agrees with the proposal of two separate standards, since there is a point of distinction recognized at 12 months. Therefore, it is necessary to adapt to the different nutritional requirements of older infants and young children, but also to address the role of different products in the diet.

We continue to support two separate standards for the follow reasons:

• The Committee has already agreed there is a recognised point of differentiation between Follow-up Formula for Older Infants and [Name of 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. This approach has created two distinctly different products both in composition and labelling i.e. Product for young children provides only a limited number of mandatory nutrients compared to Follow-up Formula for Older Infants, which mandates the addition of 32 nutrients (as agreed by the Committee currently at Step 5).

• Two separate standards provides clearer separation between Follow-up Formula for Older Infants and [Name of Product] for Young Children, which could assist to reduce the current confusion around these products.

• Given the different names, definitions, purposes, composition and labelling of these two products we believe structuring the resulting standard with two sections does not seem logical and will pose challenges because of these large differences. Naming of the standards will be simpler for two separate standards.

• Further, having two distinct standards has the potential to make updating the (separate) standard(s) easier in the future. It may also assist in progressing the discussions on preamble and scope, allowing clear differentiation between the two respective products. We do not support the option to maintain one standard with two parts.

• We note the argument for consistency with the approach taken with other Codex Standards and guidelines which are applicable to
the same age groups such as the Standard for Cereal-based foods for Infants and Young Children (STAN 74-1981), Standard for Canned Baby Foods (STAN 73-1981) and the Guidelines on Formulated Complementary Foods for older infants and young children (CAC/GL 8-1991). However in all of these cases there are minimal (if any) differences in the provisions applying to the different age groupings.

- Similarly Australia notes that this option could be argued as consistent with the approach taken for the infant formula standard which covers infant formula and formula for special medical purposes. However in this case both products are targeted at the same age group, are suitable as a sole source of nutrition and share the same composition requirements.

Brazil supports the adoption of two separate standards.

There shall be only one follow-up formula standard: The standard should not be slit into two separated standards. We support one standard with two sections.

- The Standard must be aligned with WHO 89.9 and Accompanying Guidance

Canada agrees with recommendation.

Canada has in the past noted a preference for option 2 (2 separate Standards), however we recognize that there are pros and cons for both options 1 and 2.

We support option 2 (two separate standards).

Ecuador agrees with the structure of the standard as one standard with two parts, as the categories of 6-12 months and 12-36 months are conceptually similar and both may involve the complementary nutrition of children in these age ranges. This can be justified by the fact that complementary formulas for older infants and small children are not necessary. As a result, they are products that may coexist with others during the period of complementary nutrition and both are breast-milk substitutes and must be considered as such.

As noted in the contribution to the 2018 eWG, the EU has a preference for the option proposing one standard with two parts, over the other option of two separate standards.

While it is obvious that the role in the diet of infants and young children of Follow-up Formula for older infants and [Name of Product] for Young Children changes with time, as diets progressively diversify (i.e. the product’s relative contribution to energy and nutrient requirements decreases with time) such 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 could sufficiently accommodate the different role of the products in the diet of infants and young children by having two separate parts in it. In addition, this option would be consistent with the approach taken in the Infant Formula Standard and would also be in line with what was agreed by the Committee in 2016, as detailed in the background.

The EU considers that different standards for products for older infants and young children would give excessive recognition to [Name of Product] for young children. As the European Food Safety Authority noted in 2013, 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 consider it necessary to have two separate standards for Follow-up Formula for older infants and [Name of Product] for Young Children.

Malaysia would like to reiterate our previous comments in First Consultation Paper to support Option 2 with the development of 2 separate standards for each product category with a point differentiation at 12 months, ie one standard for older infants of age 6-12 months and another standard for young children from 12-36 months.

The names of the two product categories standard have also been previously proposed by Malaysia, ie

i) Follow-up Formula (6-12 months)

ii) Formulated Milk Powder (or soy-based) product for Young Children or other similar terminology (12-36 months)

The rationale for this proposal are as follows:

a. The nutritional requirements of older infants and young children are different
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.

c. There are differences in the activity, physiological, growth and development pattern between older infants and young children.

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. 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 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.

It would be more logical, more useful and less confusing to the consumer if there are two separate products, with distinctly different nutrient composition and clearly labelled.

Nepal has always been proposing that the structure of the CODEX STAN 156-1987 should be one with two parts. These products are similar and serve as Breastmilk substitutes and therefore Nepal strongly supports that one standards for both types of products should be developed. Both types of products, Follow-up Formula for older infants and [Name of product] for young children are used as breastmilk substitutes in Nepal.

Nepal believes that the member states of the CCNFSDU have already agreed that there will be one preamble that covers both categories (6-12 months and 12-36 months) as two parts of the same standard. Thus, Nepal believes that there is no need to further reopen the matter to have two different standards and strongly opposes this. One standard with two parts is what Nepal has been expressing strongly and stands by as the products to be included in this standard are conceptually similar (a matter stated by numerous submissions to EWG 1) and so should be kept together. Furthermore, since there is a single standard for infant formula, CODEX STAN 72-1981, with two parts, having two distinct but similar products viz. infant formula and formula for special medical purposes intended for infants there is precedent for this approach. Thus, Nepal strongly believes to have one standard and two parts and NOT two separate standards. Dividing into two parts for two different age groups is justifiable, as done with a younger age group for Codex Standard for infant formula (Codex STAN 72/1981). This standard (infant formula) also has the similar structure, i.e. one standard (Codex STAN 72/1981) and two parts, one each for infant formula and the other for formula for special medical purposes for infants. This is what Nepal has been stating in our EWG consultation papers as well.

New Zealand is pleased that the essential compositional requirements for follow-up formula for older infants and [name of product] for young children have been adopted at Step 5 by CAC41 and considers that it is essential to come to an agreement on the structure at CCNFSDU40 so that Member Countries can start using the standard(s) as soon as possible.

New Zealand is of the view that two separate standards recognises these two very different products in terms of their composition, labelling and role in the diet and provides for clearer differentiation than one standard with two parts. Two standards will emphasise the fact that follow-up formula for older infants and [name of product] for young children are two distinct products. New Zealand considers that the work on both standards needs to continue in parallel and be simultaneously completed.

Sri Lanka agrees with the framework of one standard in two parts

Switzerland supports recommendation 19.

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

Switzerland prefers two separate standards.

Justification :

Two separate standards gives us the best flexibility for the future. In case of new scientific evidence, it will be possible to review separately one of the 3 product categories alone (infant formula, follow-up formula or product for young children). Furthermore, to have 3 standards, one for each product categories will differentiate with more clarity the fact that we are dealing with 3 product categories, that have different labelling and compositions requirements.
A separate Standard for the 12-36-month-old product is needed to assure these products can provide meaningful nutrition within the diverse diet of young children sufficient to assure the nutrient adequacy necessary for healthy growth and development. A separate standard better enables the nutritional composition of the product to be customized to the foods being introduced to these young children. Such a Standard is critical to make certain there are sound international specifications that assure safety, nutritional adequacy, and labelling provisions in support of regional and global trade.

The United States considers completion of the revision of the Follow-up Standard to be a priority for the Committee and considers separate standards as the most efficient approach to enable moving through the Codex approval process to formal adoption and note that there are no procedural implications other than the need to inform CAC.

The United States supports Recommendation 19 to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards. However, in addition to our earlier comments under “general comments,” the United States finds Option 2 that provides for separate standard as a practical option for several reasons:

- Two separate standards fit well within the terms of reference.
- Addresses the differences in the physiological needs for the age ranges and associated nutritional requirements for two separate products.
- Clearly distinguishes the role in the diet between these two products. (We note that the compositional requirements that have been developed over the last few years with a point of differentiation at 12 months, indicates that the FUF-OI is a nutritionally complete product that is appropriate for the 6-12 month old whereas the product for the 12-36 month old is not nutritionally complete.)
- Allows for distinct label/labelling that would clearly differentiate the products’ uses for the intended populations.

Helen Keller International, noting that both options allow for the work to be completed in the originally agreed time frame and without delay – which are important - strongly supports the structure of this Standard being one Standard with two parts. HKI reiterates that because these products are conceptually similar and serve as a liquid part of the diversified diet of older infants and young children during the complementary feeding period they should be part of the same standard.

In opening our comments on this issue, HKI draws attention to the erroneous comment made during the EWG discussion on this issue, whereby it was stated that “Many of the members supporting 2 separate standards were of the view that follow-up formula for older infants is a breast-milk substitute and nutritionally complete whereas product for young children is neither”. This is incorrect - the definition of BMS is not based on the composition of the product but on its function. Both categories of follow-up formula (6-12 months and 12-36 months) are generally used in LMIC to replace breastmilk and the WHO has been clear that infant formula and both categories of follow-up formula under discussion are considered as breastmilk substitutes.

The justification for one Standard with two parts is as follows:

1. The Committee has already agreed to the revision of the Follow-up Formula Standard with a point of differentiation of the products at 12 months and a Preamble to cover both categories 6-12 months and 12-36 months (see CCNFSDU meeting notes 2016, confirmed in CCNFSDU meeting notes 2017). Thus, one standard with 2 parts, has already been agreed and accepted and does not require further discussion.
2. Follow-up formulas and milk products for young children are not necessary. In 1986, the World Health Assembly declared that “the practice being introduced in some countries of providing infants with specially formulated milks (so-called follow-up milks) is not necessary” (WHA 39.28). These follow-up formula products are considered by many, including HKI, as having been developed as an attempt to circumvent the marketing prohibitions of the Code by claiming that they were not breastmilk substitutes. The World Health Assembly (WHA 69.9 and related Guidance on ending inappropriate promotion of foods for infants and young children), has now clarified that these products are all breastmilk substitutes. There is however merit in distinguishing the sometimes-necessary products (infant formula), which have their own standard, from these unnecessary products (follow-up formula), which should have their own standard.

Dividing a single standard of conceptually similar products into 2 parts, based on age related compositional difference, makes
logical sense and is also the approach taken in the Infant Formula Standard (CODEX STAN 72-1981). Thus, the Follow-up formula Standard would be divided into two sections with a point of differentiation at 12 months so that Part A covers the composition and labelling aspects of Follow-up Formula for Older Infants, and Part B covers the composition and labelling aspects of [Name of Product] for Young Children.

4. Precedent has been set for having a single standard with sub-divisions and, having a single standard for ‘like/conceptually similar’ products makes sense.

There is currently a single standard for infant formula (STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72 – 1981) divided into 2 parts – Section A: Standard for infant formula, and Section B: Formula for special medical purposes intended for infants. Despite these products having distinctly different purposes and composition, they form one standard.

Both products in the standard are necessary products for infants who, for whatever reason, are not breastfed. Thus, it is logical to have one standard for follow-up formula (CODEX STANDARD FOR FOLLOW-UP FORMULA CODEX STAN 156-1987) divided into 2 categories; Section A: 6-12 months, and Section B: 12-36 months. These products are conceptually similar and serve as a liquid part of the diversified diet of older infants and young children during the complementary feeding period. Both have been globally accepted as being unnecessary. The fact that they have distinctly different compositions is why there would be 2 sections to the standard (as per the Standard for Infant Formula and Formulas for Special Medical Purposes).

This approach would result in 5 standards/guidelines for foods for infants, older infants and young children that each cover a distinct product category and this approach is considered to be both logical and practical:
1. Infant formula: STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72 – 1981.

IBFAN prefers one standard for all products, infant formula, formula for special medical purposes, formulas for older infants and products for young children. If one standard for all these products is not agreed to by the Committee, IBFAN’s preference is to have one standard for the two age differentiated products – formulas for older infants and the product for young children.

The rationale for keeping these age differentiated products under one standard is to ensure that the safeguards needed for the marketing and use of these products cover both these products.

Follow-up formula were developed as a means to market infant formula and circumvent the requirements of the International Code of Marketing of Breastmilk Substitutes, claiming that follow-up formula were not covered by the Code. Hence in 1986 the 39th World Health Assembly (WHA) noted that “to achieve full implementation of and compliance with the International Code as well as the cessation of the marketing of unsuitable products and the improper promotion of breastmilk substitutes;” and endorsed the provision WHA39.28, 3.(b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called “follow-up milks” is NOT (our emphasis) necessary”. Since both these products function as breastmilk substitutes and have been determined to be non-essential it is critical that mothers, parents, be fully informed in the labelling provisions of these products. Having both of the age differentiated products under one standard facilitates common labelling provisions that are in full compliance with the International Code and subsequent WHA resolutions.

To clarify and achieve “full implementation of and compliance with” the Code and resolutions, WHA69.9 (2016) endorsed by consensus the Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children. The Guidance determined that all these products that are marketed to the age of 36 months are breastmilk substitutes. Hence having both products under one standard ensures that the Code and WHA safeguards needed to protect against the needless use of products
are in place and incorporated into the preamble and scope of these products. Whether a food is a breastmilk substitute is not dependent on whether that food is suitable for that purpose or its nutritional requirements. The Code defines a breastmilk substitutes as “any food being marketed or otherwise presented as a partial or total replacement for breastmilk, whether or not suitable for that purpose”. It should also be noted that the use of any product reduces the amount of breastmilk consumed.

ISDI takes note of the eWG recommendation for CCNFSDU to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards.

ISDI’s preferred option, outlined in CP2 Option 2: two separate standards, one for Follow-up Formula for Older Infants and one for [Name of Product] for young children). Both of these two separate standards should be progressed and be finalised in parallel and take into consideration the following elements:

- CCNFSDU36 agreed there is a recognised point of distinction at 12 months as this well reflects the need to accommodate the changing nutritional requirements of older infants and young children and allow to cater for the role of the different products in the diet.
- Two separate standards, one for Follow-up Formula for Older Infants and one for [Name of Product] for young children) could provide more clarity than option 1 considering Follow-up Formula for Older Infants (FUF) and the [Name of Product] for Young Children are two distinct products.
- There are no procedural implications in accordance with the Codex Alimentarius Commission (CAC36) mandate.
- The time to finalize the work will not be further extended.
- Proceeding with two separate standards will facilitate finalization of the respective standards in a timely manner and also allow for future potential modifications, as needed, to be efficiently addressed.

UNICEF maintains its support for the structure of this standard as one Standard with two parts.

UNICEF would like to reiterate that while infant formulas, follow-up formulas and the yet to be named milk products for young children are all breastmilk substitutes, infant formula should maintain its own standard as it is a distinct breastmilk substitute that can satisfy, by itself, the nutritional requirements of infants during the first six months. Follow-up formulas and milk products for young children are not necessary: in 1986, the World Health Assembly declared that “the practice being introduced in some countries of providing infants with specially formulated milks (so-called follow-up milks) is not necessary” (WHA 39.28). Many have considered the invention of these products an attempt to get around the marketing prohibitions of the Code by claiming that these new products were not breastmilk substitutes. This matter has now been clarified by the World Health Assembly (WHA 69.9 and related Guidance on ending inappropriate promotion of foods for infants and young children), when it called on Governments to implement the recommendations contained in the Guidance on ending inappropriate promotion of foods for infants and young children. Recommendation 2 states clearly states that “Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute 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). 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.” Hence, while there is justification for separating infant formula from the other breastmilk substitutes and maintaining a separate standard for it, given its unique characteristics as discussed above, there is no justification for separating follow-up formulas and the yet to be named milk products for young children and they should be included in a single standard.

PREAMBLE

Australia notes discussion on inclusion of a preamble has been carried over from CCNFSDU39. In the interest of progressing work on the draft Standard(s) we suggest an alternate option which may aid discussions. We propose issues related to the preamble could be addressed by a revision of the ‘Statement on Infant Feeding’ (CAC/MISC2-1976) and reinstating its original purpose. At the 11th session of the Codex Alimentarius Commission (1976) it was proposed that the Standard for Infant formula should
include a statement encouraging breastfeeding. In line with this discussion, the Commission agreed that a preamble should be included by the Secretariat indicating the policy of FAO/WHO concerning infant nutrition, including a statement that, where possible, breastfeeding should be preferred (ALINORM 76/44, paragraph 344).

In response to this decision, and to set the context/environment of the standards, the Statement on Infant Feeding was included as a preamble to the Codex Standard for Foods for Infants and Young Children, which then consisted of the Standard for Infant Formula (CODEX STAN 72-1981), Standard for Canned Baby Foods (CODEX STAN 73-1981) and the Standard for Processed Cereal-based Foods for Infants and Young Children (CODEX STAN 74-1981). However, when these three standards were disassembled as they are currently, the preamble Statement on Infant feeding because an independent document (CAC/MISC 2 - 1976).

The existence of this statement does present the option to revise and/or rescind this statement and replace it with a statement which reinstates its original purpose in the contemporary environment which can provide context for all Codex Standards for foods for infants and young children.

The Preamble for the standard and/or the scope of each category of product should make specific reference to World Health Assembly Resolution 69.9, and the labeling recommendations in the WHO guidelines Ending the inappropriate promotion of foods for infants and young children should be included in the labelling text of the standard.

- Define both the follow-up formula for 6-12 month old infants and the product for 12-36 month young children as breast-milk substitutes: These products function as breast milk substitute because their consumption replaces rather than compliments the intake of breast milk, therefore the definitions text of the standard shall directly refer to those products as breast milk substitutes.
- Policy coherent between WHA and Codex Alimentarius is critical and WHA resolution 69.9 states explicitly that these products are breast milk substitutes. In addition the text in labelling section of the standard should written so as to prevent these products from making any health or nutrition claims and prevent any form of cross promotion with similar products such as infant formula for infants less than 6 months of age.

Preamble
Ecuador believes that the words used should be “promote”, “protect” and “support” and not the word “recognise”, as “protect”, “promote” and “support” are the terms recognised around the world and are used by the World Health Organisation, the world’s top body for formulating health policy. For this reason, the initial phrase should read: “The Codex Alimentarius Commission recognises the need to protect, promote and support breastfeeding.”

It also supports the use of the word “necessary” in place of “appropriate”, as we believe that the formula should only be used when necessary on the advice of a health professional. These concepts (need and advice of a health professional) are in line with the text included in the additional labelling requirements (section 9.6) for follow-on formula for older infants, and therefore both must be used in the preamble. Therefore, the second sentence should read (underlined text added): “At the same time, the Codex recognises that a number of formulas have been produced that will only be used when necessary as a substitute for breast milk to satisfy the normal nutritional requirements of infants and small children, provided that they have been produced in hygienic conditions, are administered in adequate quantities and are only used on the advice of a health professional.”

We suggest adding the following paragraph: “Given that follow-on formulas may continue to be used beyond six months, these products are not indispensable.” The production, distribution, sale and use of complementary formulas for older infants and [name of product] for children “should only be permitted if it is compatible” with the relevant national health and nutrition policies and national/regional legislation. The marketing of these products should not discourage breastfeeding and should be in line with the recommendations formulated in the International Code of Marketing of Breast-Milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and the relevant guidelines and policies of the World Health Organisation (WHO) as well as the relevant resolutions of the World Health Assembly (WHA). We suggest adding: “including Resolution 69.9 (2016) of the WHA and WHO Guidance on ending the inappropriate promotion of foods for infants and young children.”

The Codex Alimentarius Commission acknowledges the need to [protect and support] Breastfeeding as an unequaled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous

<table>
<thead>
<tr>
<th>Country</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Cambodia</td>
<td>The Preamble for the standard and/or the scope of each category of product should make specific reference to World Health Assembly Resolution 69.9, and the labeling recommendations in the WHO guidelines Ending the inappropriate promotion of foods for infants and young children should be included in the labelling text of the standard.</td>
</tr>
<tr>
<td>Ecuador</td>
<td>Preamble Ecuador believes that the words used should be “promote”, “protect” and “support” and not the word “recognise”, as “protect”, “promote” and “support” are the terms recognised around the world and are used by the World Health Organisation, the world’s top body for formulating health policy. For this reason, the initial phrase should read: “The Codex Alimentarius Commission recognises the need to protect, promote and support breastfeeding.”</td>
</tr>
<tr>
<td>Egypt</td>
<td>Egypt supports the words (Protects and supports)</td>
</tr>
<tr>
<td>Country</td>
<td>Comments</td>
</tr>
<tr>
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</tr>
<tr>
<td>India</td>
<td>The Codex Alimentarius Commission acknowledges the need to protect and support breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants and Young Children. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where appropriate, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding. The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, as appropriate, the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been endorsed by member states provide guidance to countries in this context.</td>
</tr>
<tr>
<td>Jamaica</td>
<td>The Codex Alimentarius Commission acknowledges the need to protect and support breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where appropriate, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding. The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, as appropriate, the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and subsequent World Health Assembly (WHA) Resolutions, as well as the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions policies that have been endorsed by member states may also provide guidance to countries in this context.</td>
</tr>
<tr>
<td>Nepal</td>
<td>Nepal supports the referencing of WHA resolutions, and agrees to the fact that the referencing will appear in the preamble or in the scope sections of two types of product categories. Nepal reiterates that the WHA resolutions, including WHA 69.9, should be placed either in the preamble of the standard or in the scope section of both products, once the structure of the standard is determined. Further comments to the existing texts in the preamble include: 1. Nepal strongly support the word “Protect and Support” and NOT “recognize” as the word recognize may dilute the importance of breastfeeding. The Codex Alimentarius Commission, a joint committee of FAO/WHO, needs to use terminologies similar to that used at various WHO documents, which includes the term “protect and support”, rather than recognize. 2. Nepal supports the use of the word “necessary” since breastmilk substitutes are used only when they are necessary. 3. Nepal proposes to delete the word [as appropriate] from the third line of the second paragraph. Furthermore, Nepal strongly believes in using the word “endorsed”, as Nepal had endorsed the WHA resolutions during the WHA 69 meeting. Nepal and not recognize. Because the words protect, promote and support are the globally recognized terminology and the wording used by the World Health Assembly. Egypt supports the word (Necessary) rather than appropriate as the use of formula should only be used where necessary on the advice of a health worker. As well as that the word “necessary” will be compatible with clause 9.6.1 c “Additional Labelling Requirement” which stated that “the product should only be used on advice of a health worker as to the need for its use and the proper method of use.</td>
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further believes that the words [may also] is not relevant since, these WHA resolutions do provide guidance to country like ours.

The Codex Alimentarius Commission acknowledges the need to [protect and support / recognize] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.

Philippines

We are of the opinion that the “protect and support” are the most appropriate terms to refer to breast feeding as the gold standard in food for growth and development of infants. We also agree that the intended use for follow up formula, where appropriate as a substitute for human milk in meeting the nutritional needs of infants meeting the hygienic and adequacy requirements. The Philippines supports deletion of "as appropriate" in this statement "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 Breast-milk Substitute (1981) and the Global Strategy of Infant and Young Child feeding". Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been supported by member states provide guidance to countries in this context. We support deletion of "may also" since it should be definite that the International Code of Marketing Breastmilk Substitute and relevant WHA resolutions provide firm guidance to countries in policies on infant and young child feeding.

Sri Lanka notes the existing agreement of the CCNFSDU that reference to WHA resolutions will appear either in the Preamble or in the individual Scope text of the 2 categories of product under consideration. "protect and support breastfeeding" is the globally used terminology

The Codex Alimentarius Commission acknowledges the need to [protect and support / recognize] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.

Sri Lanka

The US recalls that the ToR agreed to by the Committee prioritized finalizing the essential composition, product definitions, and labelling requirements as well as developing proposals for the scope and considering options for the structure of the standard. It is the view of the US that the Committee remain focused on completing the important work of finalizing the structure, scope, compositional and labeling parts of the standard during this year’s meeting. The US suggests that the preamble discussion occur after finalizing other elements of the standards as the decisions on scope, labelling, definitions, and structure will impact the scope of the preamble. Thus, the US supports finalizing the essential composition, labelling, scope, and product definition pieces of the
standard to progress the work on this Standard. The US is of the view that it is necessary to have robust discussion of the structure and deliberate consideration of the advice from CCEXEC75 before the discussing the Preamble text.

The US notes the advice from CCEXEC75 and agrees that including references in standards should be considered on a case-by-case basis as appropriate for providing context and supports inclusion of additional technical and science based information to assist members in better understanding the basis and use of standards.

The US supports the CCEXEC advice that 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.

HKI notes the existing agreement of the CCNFSDU that reference to WHA resolutions will appear either in the Preamble or in the individual Scope text of the 2 categories of product under consideration. HKI notes that such referencing is in line with the text recorded in the report of the 75th Session of the Executive Committee of the Codex Alimentarius Committee (REP18/Exec2-Rev.1).

HKI therefore reminds the Committee that the positioning of the references to WHA resolutions is still under discussion and reserves the right to decide on where it recommends the placement of such references, including reference to WHA Resolution 69.9, once the discussion as to the structure of the Standard has been concluded.

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 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, and only used on the advice of a health worker. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, as 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, and only used on the advice of a health worker. These concepts – necessity and on advice of a health worker - have already been agreed in the text included under Additional Labelling Requirement (Clause 9.6) of the follow-up formula for older infants product category and so should both be used in the Preamble. Thus, the second sentence would read “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.”

HKI also supports the use of the word ‘necessary’ rather than ‘appropriate’ as we believe that the use of formula should only be used where necessary on the advice of a health worker. These concepts – necessity and on advice of a health worker - have already been agreed in the text included under Additional Labelling Requirement (Clause 9.6) of the follow-up formula for older infants product category and so should both be used in the Preamble. Thus, the second sentence would read (underlined text added), “At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions, are given in adequate amounts, and only used on the advice of a health worker.”

HKI strongly believes that the words [as appropriate] should be deleted and be replaced with the wording used in World Health Assembly (WHA) resolutions, which usually use the terminology that Codex should ‘give full
consideration’ to WHO guidelines and recommendations, including the international code of marketing of breast milk substitutes and relevant WHA resolutions. Further, with regards to the use of the word ‘endorsed’ or ‘supported’, HKI strongly supports the use of the term endorsed when it comes to reference to resolutions of the WHA that have been endorsed, as is the case with the relevant resolutions being considered in this matter. HKI also believes that the [may also] is not necessary.

Thus HKI proposes that the second paragraph should read, “The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate,] give full consideration to the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.

Remove brackets as indicated.

The Codex Alimentarius Commission acknowledges the need to protect and support exclusive breastfeeding for the first six months of life and sustained breastfeeding to two years or beyond as an unequalled way of providing the normal 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 nutritional requirements of infants provided they are prepared as directed, 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 are classified as breastmilk substitutes, are NOT necessary to meet the nutritional requirements of young children and should not undermine breastfeeding.

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be permitted only if it is consistent with national health and nutrition policies and relevant national/regional legislation, and conform to 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 has have been endorsed and supported by member states shall also provide guidance to countries in this context.

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the

IBFAN

The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context. The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.

UNICEF

- UNICEF prefers the use of the wording calling for the need to ‘protect and support’ breastfeeding as opposed to the word ‘recognize’. The need to protect and support breastfeeding in the face of unethical marketing practices and inappropriate hospital practices led to the need for the adoption of the International Code of Marketing of Breastmilk Substitutes and the Baby Friendly Hospital Initiative, among others. The opening sentence should thus read “The Codex Alimentarius Commission acknowledges the need to protect breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants.”
- The word ‘necessary’ should be adopted rather than ‘appropriate’, in line with the aim of the International Code which is stated to include “ensuring the proper use of breast-milk substitutes, when these are necessary”. Given the documented risks of not breastfeeding to the health of the mother and child, it is important that they are only used when necessary, and on the advice of a health worker as per the Code. The second sentence should thus read “At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions, are given in adequate amounts.”

While it has not yet been agreed as to whether reference to relevant World Health Assembly resolutions will appear in the Preamble or in the text of the individual Scope provisions for follow-up formula for older infants and the yet to be named milk products for young children, UNICEF will provide further opinion on the placement of such references until discussion of the structure of the Standard has been concluded.
- The words “[as appropriate]” should be deleted. In adopting the International Code in 1981, the WHA stressed that “the adoption of and
adherence to the International Code of Marketing Breast-milk Substitutes is a minimum requirement”. This was reiterated by the Assembly in 1982, 1992 and 2002. Furthermore, The Assembly has requested “the FAO/WHO Codex Alimentarius Commission to give full consideration, within the framework of its operational mandate, to action it might take to improve the quality standards of infant foods, and to support and promote the implementation of the International Code”. With regards to the use of the word ‘endorsed’ or ‘supported’, UNICEF believes that neither of these terms is appropriate in relation to WHA resolutions, since to be adopted as a resolution they must have the support of member states. The use of the words [may also] is superfluous and should be struck through.

The second paragraph should thus read, “The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.

SPECIFIC COMMENTS
SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

Recommendation 1, 2, 3

1 [SCOPE]

1.1 This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as Follow-up Formula for Older Infants.

For recommendations 1, 2, 3, Australia supports the text proposed by the Chairs.

Australia
Brazil agrees with Recommendations 1, 2, 3
Brazil
Canada agrees with recommendations 1, 2, 3.
Canada
Colombia supports proposed text and requests clarification on the exclusion of food for special medical purposes for Colombia
<table>
<thead>
<tr>
<th>Country</th>
<th>Text</th>
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<tbody>
<tr>
<td>Costa Rica</td>
<td>This age group.</td>
</tr>
<tr>
<td></td>
<td>Costa Rica supports Recommendation 1.1 and 1.2, recognising that the current document lacks specifications regarding analytical methods, but it hopes that they will be discussed at a later stage. Costa Rica supports this Recommendation 1.3 as well as maintaining the phrase “will be presented”, as this is in line with the terminology used in the section of the standard on labelling.</td>
</tr>
<tr>
<td>Cote d’Ivoire</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cote d’Ivoire supports the proposal as formulated in 1.2.</td>
</tr>
<tr>
<td>Ecuador</td>
<td>We suggest adding “warnings against the unnecessary and inappropriate use” labelling and analytical requirements for complementary formulas for older infants.</td>
</tr>
<tr>
<td>Egypt</td>
<td>Only products that comply with the criteria laid down in the provisions of this section of this Standard [should/ shall] be presented as Follow-up Formula for Older Infants.</td>
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<tr>
<td>EU</td>
<td>The EU agrees with the proposed text in 1.1. The EU can accept the Chairs’ proposal that Section 1.2 of the Scope for follow-up formula for older infants be expanded to reference the labelling and analytical requirements within the Standards. The EU agrees with the Chairs’ recommendation 3. As noted on previous occasions, the EU strongly supports the use of “shall” in the text in order to ensure consistency with the terminology used in the labelling section of the Standard.</td>
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<td>Ghana</td>
<td>We support the text in the section 1.1, 1.2 (removal of the square brackets) and 1.3 (We support the use of shall as it is consistent with standard Codex texts. We therefore recommend the removal of the square brackets)</td>
</tr>
<tr>
<td>India</td>
<td>Only products that comply with the criteria laid down in the provisions of this section of this Standard [should/ shall] be presented as Follow-up Formula for Older Infants subject to National Regulations.</td>
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<td></td>
<td>The resolution WHA 69.9 and Guidance on ending the inappropriate promotion of foods for infants and young children, has defined a breast milk substitute unambiguously as “A breast-milk substitute 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);” Hence the marketing of “Follow-up formula for older infants;” shall come under the purview of and guided by national regulations and International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions and this fact should be reflected in the Scope.</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Indonesia supports the proposed text in 1.1 and supports to open the square brackets in 1.2 and text as proposed in 1.3</td>
</tr>
<tr>
<td>Mali</td>
<td>Mali approves the text as proposed in 1.1, 1.2</td>
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<tr>
<td>Norway</td>
<td>We agree with the proposal in 1.1, 1.2, 1.3.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Recommendation 1: New Zealand agrees to the text for Section 1.1 as presented. Recommendation 2: New Zealand agrees to the text for Section 1.2 as presented.</td>
</tr>
<tr>
<td>Recommendation 3:</td>
<td>New Zealand supports the statement proposed for Section 1.3 of the Scope for follow-up formula for older infants. We acknowledge that ‘shall’ is consistent with the terminology used in the labelling section of the standard and therefore this is our preferred wording.</td>
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<tr>
<td><strong>We support the retention of the statements in 1. Scope 1.1.,1.2. and 1.3 with the use of “shall” in Statement 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as Follow-up Formula for Older Infants.</strong></td>
<td><strong>Philippines</strong></td>
</tr>
<tr>
<td>This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.</td>
<td><strong>USA</strong></td>
</tr>
<tr>
<td>The United States supports Recommendation 1 as stated with the following suggested edit bracketed in bold for clarity of the product’s identity.</td>
<td><strong>Senegal</strong></td>
</tr>
<tr>
<td>The United States supports Recommendation 2 with removal of the square brackets and retaining labeling and analytical.</td>
<td><strong>Switzerland</strong></td>
</tr>
<tr>
<td>The United States supports Recommendation 3 as stated below with the removal of the square brackets and “shall” accepted.</td>
<td><strong>EU Specialty Food Ingredients</strong></td>
</tr>
<tr>
<td><strong>Switzerland supports recommendation 1, 2 and 3.</strong></td>
<td>As analytical requirements are not specifically covered, EU Specialty Food Ingredients believes they should be removed.</td>
</tr>
<tr>
<td><strong>1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.</strong></td>
<td><strong>IBFAN</strong></td>
</tr>
<tr>
<td><strong>HKI supports the proposed text in 1.1, 1.2 and 1.3</strong></td>
<td><strong>ISDI supports recommendation 1</strong></td>
</tr>
<tr>
<td><strong>ISDI supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are</strong></td>
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related to composition, quality and safety – similar to contaminants.
ISDI supports this recommendation 3 and favours the word “shall” instead of “should” as this is more consistent with the terminology used in the labelling section of the Standard.

Remove square brackets and strikethrough the word ‘should’

### Recommendation 7

#### 2 DESCRIPTION

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<th>2.1 Product Definition</th>
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<tbody>
<tr>
<td><strong>2.1.1</strong> [Follow-up formula for older infants means a product, specially manufactured for use as a substitute for breast-milk, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.]</td>
</tr>
<tr>
<td><strong>2.1.2</strong> Follow-up formula [for older infants] is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.</td>
</tr>
</tbody>
</table>

#### Support 2.1.1

**Australia**
We consider the removal of the word ‘specially’ is appropriate as it is a breast milk substitute. The inclusion of the text ‘as a substitute for breast-milk’ clarifies this.

**Brazil**
We believe that the definition should clearly state that follow-up formula is a product manufactured for use as a substitute for breast-milk for consistency with WHO documents. We consider that it is also important to clearly distinguish the differences between follow-up formula and other liquid foods intended to older infants.

#### Support 2.1.1

**Cambodia**

2.1.1-[Follow-up formula for older infants means a product, specially manufactured for use as a substitute for breast-milk, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.]

**Support 2.1.1**

**Canada**

**Colombia**

2.1.1
Although the product, according to the standard, is nutritionally equivalent to breast milk, Costa Rica, as indicated during the consultations of the Electronic Working Group, supports the definition retaining the word “specially” and eliminating the phrase “as a breast-milk substitute”.
The term “specially” has been utilised in the wording of various Codex standards, such as Codex STAN 146-1985, Codex STAN 72-1981, Rev. 2007 y CAC / GL 8-1991, Rev. 2013) related to foods for infants and young children that affirm that these products are “specially manufactured/formulated”.
The Standard for Infant Formulas (CX STAN 72-1981) defines infant formula as a breast-milk substitute and affirms that “No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life”. Follow-on formulas are manufactured specially for use as the liquid part of a progressively diversified diet for older infants. These products do not, by themselves, satisfy the nutritional requirements of older infants. As such, it is potentially misleading to affirm that they may be used as a substitute for breast milk or as a replacement for infant formula.

**Costa Rica**

**Cote d’Ivoire**

Support 2.1.1

**Egypt**

**Ghana**

Support 2.1.1
| Support 2.1.2 | We agree with the description of the product and the insertion of substitute for breastmilk. |
| Support 2.1.1 | Indonesia |
| 2.1.1 [Follow-up formula for older infants means a product, specially manufactured for use as a partial or total substitute for breast-milk, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.] | Malaysia |
| 2.1.1 Mali accepts the text as proposed, with the deletion of the brackets and the word "especially" | Mali |
| 2.1.2 Mali approves the text as proposed | New Zealand |
| 2.1.1 Follow-up formula for older infants means a product, manufactured for use as a substitute for breast-milk, as a liquid part of a progressively diversified diet when complementary feeding is introduced. | Peru |
| 2.1.1 The Commission proposes leaving the word “specially”, as these types of products involve a special production process. It also proposes eliminating the phrase “as a substitute for breast milk” for the following reasons: • Limiting the substitute for breast milk to products for infants ages 6 to 12 months would confuse consumers and potentially result in serious consequences for children’s health if care providers believed that these products were breast-milk substitutes, i.e. sole sources of nutrition. • Products for infants ages 6 to 12 months are not designed to provide all of the essential nutrients provided by breast milk. Follow-on formulas are not a sole source of nutrition. They are designed to be used as the liquid part of a progressively diversified diet for older infants. Therefore, these products do not satisfy, by themselves, the nutritional requirements for older infants. • Including the phrase “as a substitute for breast milk” in the definition means that it may be used on the product label, which would cause confusion about the nature of the product and result in the inappropriate use of these products as substitutes for breast milk. In addition, this is not in line with the provisions of Section 9.6 regarding additional labelling requirements, which specifies that labels must not discourage breastfeeding. • Restricting the communication of these products and their dietary role may result in unfair competitive conditions and favour the selection of foods that are not suitable for older infants and small children. • Codex Stan 72 defines infant formula as a breast-milk substitute and declares that “No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of infants during the first six months of life” | Philippines |
| The Philippines supports the retention of the bracketed statement 2.1.1. Product Definition “Follow-up Formula for older infants means a product manufactured for use as a substitute for breast-milk, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.”. We are of the opinion that the term... |
| **“specially” is not appropriate in this statement, hence we support its deletion.** |
| Senegal |
| Recommendation 7  |
| Position: Senegal approves the text as proposed and accepts the deletion of the word “especially” |
| Switzerland support recommendation 7 (2.1.1) |
| USA |
| The United States supports Recommendation 7 the definition for follow-up formula for older infants with removal of the square brackets and deletion of specially and has a suggested edit for consistency. |
| Viet Nam |
| 2.1.1 [Follow-up formula for older infants means a product, specially manufactured for use as a substitute for breast-milk breast-milk substitute, as a liquid part of a progressively diversified diet for older infants when nutritionally adequate complementary feeding is introduced.]
| EU Speciality Food Ingredients |
| 2.1.1 Follow-up formula for older infants means a product, specially manufactured for use as a substitute for breast-milk breast-milk substitute, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced. |
| HKI |
| HKI agrees to all the recommended text changes - the removal of the square brackets, strikeout of the word ‘specially’ and inclusion of the words ‘as a substitute for breast-milk’. HKI suggests however that the wording ‘as a substitute for breast-milk’ be changed to be in line with the global terminology and so reads ‘as a breast-milk substitute’ but will not object to it remaining as presented. |
| IBFAN |
| 2 DESCRIPTION  |
| 2.1 Product Definition  |
| 2.1.1 Follow-up formula for older infants means a product, manufactured for use as a substitute for breast-milk substitute as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced. |
| 2.1.2 Follow-up formula for older infants is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold. |
| ISDI |
| ISDI supports the definition as shown in track changes. ISDI considers that the wording “as a substitute for breast milk” is |

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**Translation:**

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

---

**Excerpt:**

- Switzerland: Support recommendation 7 (2.1.1)
- USA: The United States supports Recommendation 7 the definition for follow-up formula for older infants with removal of the square brackets and deletion of specially and has a suggested edit for consistency.
- Viet Nam: 2.1.1 [Follow-up formula for older infants means a product, specially manufactured for use as a substitute for breast-milk substitute, as a liquid part of a progressively diversified diet for older infants when nutritionally adequate complementary feeding is introduced.]

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**Excerpt:**

- Senegal: Recommendation 7 Position: Senegal approves the text as proposed and accepts the deletion of the word "especially"
not suitable in the definition of Follow up Formula for older infants.
ISDI takes note of the discussions at CCNFSDU39 and the analysis of the eWG Chair.
• With regard to the word “specially”, ISDI is of the opinion that it is appropriate to retain the word. Older infants have particular nutritional requirements and this product aims to address these.
Follow-up formula for older infants remains a “food for special dietary uses” in line with the GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 146-1985) that describes “Foods for Special Dietary Uses (FSDU) are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.”
ISDI would like to highlight that the last revised Standard for infant formula and formula for special medical purposes intended for infants (Codex STAN 72-1981, rev.2007) and the Guidelines on formulated complementary foods for older infants and young children (CAC/GL 8-1991, rev. 2013) stipulate these products are “specially manufactured” and “specifically formulated” respectively. Both are Foods for Special Dietary Uses and the terminology “specially manufactured”/ “specifically formulated” refers to the nutritional requirements provided by these products.
• With regard to the reference ‘substitute for breast milk’, ISDI notes that CX STAN 72-1981 defines infant formula as a breast-milk substitute and states that “No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.”
Follow-up formulas do not constitute the sole source of nutrition. They are intended for use as a liquid part of a progressively diversified diet for older infants. Therefore, these products do not satisfy, by themselves, the nutritional needs of the older infant.
ISDI notes that the requirements not to discourage breastfeeding are stipulated in section 9.6 (Additional Labelling Requirements).

Support 2.1.1

UNICEF
Remove square brackets in 2.1.1, delete the word ‘specially’ (which would tend to idealise the product in violation of the International Code) and include the words ‘as a substitute for breast-milk’ in accordance with Recommendation 2 of the Guidance on ending inappropriate promotion of foods for infants.
2.2 Other Definitions

2.2.1 The term *infant* means a person of not more than 12 months of age.

2.2.2 The term *older infant* means a person from the age of 6 months and not more than 12 months of age.

Colombia supports proposed text.

We support the definitions in the section.

Mali accepts the text as proposed.

**Recommendation 9**

9. **[LABELLING]**

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1–1985)*, the *Guidelines on Nutrition Labelling (CXG 2–1985)* and the *Guidelines for Use of Nutrition and Health Claims (CXG 23–1997)* apply to follow-up formula for older infants. [These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.]

Australia notes the Codex Procedural manual states text from other Codex documents should not be reported, instead a reference to the relevant documents should be included. As the text in square brackets is already covered in the Guidelines for Use of Nutrition and Health Claims we can SUPPORT deletion of the text.

Brazil would like to request clarification about Recommendation 9, specially about the decision to delete the statement ‘These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation’. In this regard, we consider that the text contained within the square brackets (in bold) should be retained. However, if the Committee agrees to delete the sentence, we consider that it is necessary to include a new specific item in the labelling requirements which clearly states that nutrition and health claims shall not be permitted for FUF.

Colombia considers that text in brackets can be deleted considering that conditions for using nutritional and health claims are explicit in CAC/GL 23-1997 (number 1.4). We recommend reviewing the nomenclature (CXG 23 or CAC/GL 23).

Cote d’Ivoire approves the text as proposed (with deletions).

Ecuador

9. Ecuador does not agree with the elimination of the phrase “These requirements include the prohibition against making nutritional and health claims for foods intended for infants and young children except in cases specifically allowed under the relevant Codex standards or in national legislation”.

Currently, none of the relevant Codex standards permits claims...
The Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) already covered this point and stated that clearly in the Scope (1.4), so no need to repeat the sentence.

Egypt

The EU agrees with the Chairs` recommendation.
As noted previously, the text in square brackets is already covered by the referenced Guidelines for Use of Nutrition and Health Claims and it is therefore redundant.

EU

We support the removal of the square brackets and the text. The Codex Standard and Guidelines mentioned in the text are exhaustive.

Ghana

The deleted text in square brackets should be retained to reiterate and clarify that nutrition and health claims are not appropriate for older infants.

India

The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

Indonesia

Indonesia does not agree with the deletion of the last sentence. This sentence is necessary to emphasize and clarify the requirement related to claims for infant and young children in the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997). Indonesia would like to propose the following changes:

Mali accepts the text as proposed.

Mali

New Zealand
Recommendation 9:
New Zealand supports the proposed introductory paragraph to the Labelling Section for follow-up formula for older infants and the deletion of the text.

New Zealand

Norway
We continue to support the text that explains that the requirements in the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) include a prohibition on the use of nutrition and health claims. We consider it important to highlight the prohibition on the use of nutrition and health claims for foods for infants and young children. Furthermore, this is consistent with the Infant Formula Standard.

We recognise there is no procedural impediment to duplicate what is already covered by the Nutrition and Health Claims guidelines. Furthermore, in this case we consider it particularly relevant and essential to reiterate the prohibition in this standard.

Norway
| **Philippines** | The Philippines supports this statement to reiterate the prohibition of health and nutrition claims for foods for infants and young children as provided and in compliance with the Codex Guidelines on Health and Nutrition Claims for Food Use. While this is already covered by the Nutrition and Health Guidelines, it is still necessary to emphasize that all types of health and nutrition claims should not be allowed on labels of follow up formula for older infants. We believe that the proposed statements are sufficient to prevent any claims on follow up formula. To date, no health and nutrition claims are allowed on any Codex Standards for foods for infants and young children. |
| **Senegal** | Recommendation 9  Position: Senegal approves the text as proposed, with deletions. |
| **Switzerland** | Switzerland supports the prohibition of the use of nutrition and health claims on foods for infants and young children, for clarity and consistency reasons we would like to keep the text [These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.]
| **USA** | The United States supports Recommendation 9 on the text for the introductory paragraph to the Labelling Section for follow-up formula for older infants and the deletion of Codex prior to the General Standards title. |
| **HKI** | Hong Kong supports the recommendation as proposed with the deletion of the strikethrough. |
| **ISDI** | ISDI supports this recommendation. |
| **UNICEF** | The World Health Assembly first expressed its concern in 2005 that “nutrition and health claims may be used to promote breastmilk substitutes as superior to breastfeeding”, calling on Governments to “ensure that nutrition and health claims are not permitted for breast-milk substitutes, except where specifically provided for in national legislation”. This was reiterated in 2010 when the Assembly called on Governments to “ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation. Despite these warnings, manufacturers of breastmilk substitute products continue to make claims that are not supported by scientific evidence.” |

We propose to retain the statement “These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.”

The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to follow-up formula for older infants. [These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.] The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to follow-up formula for older infants. [These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.]
substitutes continue to make such claims on labels of their products around the world, as demonstrated in IBFAN’s Breaking the Rules, Stretching the Rules 2017 global Code monitoring report:

“Unfounded health claims. Claims have become a prime marketing tool. Adding complicated ingredients to formula gives rise to ever more health claims protecting the baby from everything and anything. Many of these additives are then used as trademarked logos, mascots or benefit icons, to protect the company’s exclusive usage. More importantly, such logos and icons serve to push ‘fortified’ or “premium-ised” formulas without having to use brand names, circumventing the Code.”

Given the emphasis the World Health Assembly has placed on the need to prohibit health and nutrition claims in respect of the products subject to the standard under consideration, and the continued, well-documented use of such claims by the manufacturers of these products, it is in the best interest of infants and young children that the prohibition be stated clearly in the standard.

<table>
<thead>
<tr>
<th>9.1 The Name of the Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colombia supports proposed text.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9.1.4 support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egypt</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>9.1.3 c) The introduction of this subsection is important to cover the other sources of protein and milk that may be used in the manufacture of the product. We therefore support the subsection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghana</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>9.1.3 c) If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein’ or ‘Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein’ with the main source being mentioned first.</th>
</tr>
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<tbody>
<tr>
<td>India</td>
</tr>
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</table>

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<tr>
<th>9.1.3c) If [name of animal] milk and [name of plant] are the sources of protein[<em>], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein’ or ‘Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein’. If [name of animal] milk and [name of plant] are the sources of protein[</em>], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein’ or ‘Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein’ in order to descending</th>
</tr>
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<tbody>
<tr>
<td>Iran</td>
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</tbody>
</table>

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<thead>
<tr>
<th>9.1.1, 9.1.2, 9.1.3a), b), c) including * ; 9.1.4 Mali accepts the text as proposed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mali</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9.1.4 Retention of ‘shall’ in this statement is preferred 9.1.4 A product which contains neither milk nor any milk derivative shall be labelled &quot;contains no milk or milk products&quot; or an equivalent phrase.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philippines</td>
</tr>
</tbody>
</table>
We support retention of the bracketed statement “For clarity, addition of individual amino acids where needed to improve protein quality does not preclude us of the above labeling options”.

| 9.1.2 | HKI supports the text as proposed – deletion of square brackets |
| 9.1.3a) | If [name-name of animal] animal milk is the only source of protein[*] protein, the product may be labelled 'Follow-up Formula for Older Infants Based on [name-name of animal] animal milk [protein] protein. |
| 9.1.3b) | If [name-name of plant] plant is the only source of protein[*] protein, the product may be labelled 'Follow-up Formula for Older Infants Based on [name-name of plant] [protein] plant protein. |
| 9.1.3c) | If [name-name of animal] animal milk and [name-name of plant] plant are the sources of protein[*]protein, the product may be labelled 'Follow-up Formula for Older Infants Based on [name-name of animal] animal milk protein and [name-name of plant] plant protein' or 'Follow-up Formula for Older Infants Based on [name-name of plant] [protein] plant protein and [name-name of animal] animal milk protein'. |

* [* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

| 9.1.4 | HKI supports the text as presented - the strikethrough of 'may' and deletion of the square brackets around 'shall' |

| 9. LABELLING Remove brackets |
| The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. |

| 9.1.1 | The Name of the Product |
| The text of the label and all other information accompanying the product shall be written in the appropriate language(s). |

| 9.1.2 | The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national usage. |

| 9.1.3 | The sources of protein in the product shall be clearly shown on the label. |
| a) If name of animal milk is the only source of protein, the product may be labelled 'Follow-up Formula for Older Infants Based on name of animal milk protein. |
| b) If [name of plant] is the only source of protein[*], the product may be labelled ‘Follow-up Formula for Older Infants Based on name of plant protein. |
| c) If name of animal milk and name of plant are the sources of protein, the product shall be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk protein and name of plant protein' or 'Follow-up Formula for Older Infants Based on [name of plant] protein and name of animal milk protein'. |

For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.
<table>
<thead>
<tr>
<th>Clause</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1.4</td>
<td>A product which contains neither milk nor any milk derivative shall be labelled “contains no milk or milk products” or an equivalent phrase.</td>
</tr>
<tr>
<td>9.1.2</td>
<td>agree with deletion of square brackets</td>
</tr>
<tr>
<td>9.1.3a), b), c)</td>
<td>Agreed with the removal of all square brackets.</td>
</tr>
<tr>
<td>9.1.4</td>
<td>Agreed with the deletion of the word ‘may’ and the deletion of the square brackets around ‘shall’.</td>
</tr>
<tr>
<td>9.2</td>
<td>List of Ingredients</td>
</tr>
<tr>
<td>9.2.1</td>
<td>A complete list of ingredients [including optional ingredients] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.</td>
</tr>
<tr>
<td></td>
<td>agree with the deletion of the strikethrough text</td>
</tr>
<tr>
<td></td>
<td>9.2.1 A complete list of ingredients including optional ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.</td>
</tr>
<tr>
<td></td>
<td>Mali accepts the text as proposed.</td>
</tr>
<tr>
<td></td>
<td>We support deletion of the bracketed phrase “including optional ingredients”</td>
</tr>
<tr>
<td></td>
<td>HKI supports the deletion of the strikethrough text.</td>
</tr>
<tr>
<td></td>
<td>Agreed with the deletion of the strikethrough text.</td>
</tr>
<tr>
<td></td>
<td>Mali accepts the text as proposed.</td>
</tr>
<tr>
<td></td>
<td>We support the subsection as it re-enforces the requirement for listing ingredients used in the manufacture of the product.</td>
</tr>
<tr>
<td></td>
<td>Malaysia does not agree the recommendation in paragraph 9.2.2 which specific name for food additive should be declared as it is not in line with the paragraph 4.2.3.3 in General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).</td>
</tr>
<tr>
<td></td>
<td>Mali accepts the text as proposed and is in favour of deleting the brackets</td>
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<tr>
<td></td>
<td>We support retention of the bracketed statement “The food additives INS number may also be optionally declared.”</td>
</tr>
<tr>
<td></td>
<td>HKI supports the proposed text and the deletion of the square brackets and strikethrough text.</td>
</tr>
<tr>
<td>9.2</td>
<td>List of Ingredients</td>
</tr>
<tr>
<td>9.2.1</td>
<td>A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.</td>
</tr>
<tr>
<td>9.2.2</td>
<td>The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared.</td>
</tr>
<tr>
<td></td>
<td>Agree with text</td>
</tr>
<tr>
<td></td>
<td>We support the subsection as it re-enforces the requirement for listing ingredients used in the manufacture of the product.</td>
</tr>
<tr>
<td></td>
<td>Malaysia does not agree the recommendation in paragraph 9.2.2 which specific name for food additive should be declared as it is not in line with the paragraph 4.2.3.3 in General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).</td>
</tr>
<tr>
<td></td>
<td>The standard CXS 1-1985 requires the functional classes shall be used together with the specific name or recognized numerical identification such as the Class Name and the International Numbering System for Food Additive (CXG 36-1989) as required by national legislation.</td>
</tr>
<tr>
<td></td>
<td>Mali accepts the text as proposed and is in favour of deleting the brackets</td>
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<td></td>
<td>We support retention of the bracketed statement “The food additives INS number may also be optionally declared.”</td>
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<td></td>
<td>HKI supports the proposed text and the deletion of the square brackets and strikethrough text.</td>
</tr>
<tr>
<td></td>
<td>IBFAN</td>
</tr>
</tbody>
</table>
addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared.

Agreed with the inclusion of the proposed text and the deletion of the square brackets and strikethrough text.

<table>
<thead>
<tr>
<th>9.3 Declaration of Nutritive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colombia supports proposed text.</td>
</tr>
<tr>
<td>9.3 a) India suggests that bracketed text [as well as] should be included.</td>
</tr>
<tr>
<td>9.3 b) India suggests that bracketed text [as well as] should be included.</td>
</tr>
<tr>
<td>9.3 a), b), c) Mali accepts the text as proposed.</td>
</tr>
<tr>
<td>9.3, 9.3a), b) HKI supports the proposed text</td>
</tr>
<tr>
<td>9.3 Declaration of Nutritive Value</td>
</tr>
<tr>
<td>The declaration of nutrition information for follow-up formula for older infants shall contain the following information, which should be in the following order:</td>
</tr>
<tr>
<td>a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</td>
</tr>
<tr>
<td>b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</td>
</tr>
<tr>
<td>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</td>
</tr>
</tbody>
</table>

| 9.3 a) b) c) Agreed with deletion of square brackets and strikethrough text. |

<table>
<thead>
<tr>
<th>9.4 Date Marking and Storage Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colombia supports proposed text. The date marking text for follow-up formula for older infants and that for the yet unnamed product for young children should be the same, and supports the use of the text proposed for the latter for both categories of product</td>
</tr>
</tbody>
</table>

| 9.4.1 (i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).] |

| Codex Stan 1 as mentioned in the labelling section gives comprehensive requirements for date marking in Section 4.7.1 (ii - viii). We therefore see this section as a repetition. |

| Cote d’Ivoire |
| Position: 9.4.1 i) and 9.4.2: Cote d’Ivoire supports the proposals. |

| Mali |
| Accepts the text as proposed. |

| Philippines |
| The Philippines supports deletion of the brackets for 9.4.1. |
9.4.1 (i) The "Best Before Date" or "Best Quality Before Date" shall be declared by the day, month and year except that for products with a shelf-life of more than three months, at least the month and year shall be declared. The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).

(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words "Best before end <insert date>; or "Best Quality before end <insert date>.

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if required to support the integrity of the food and, where the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.

HKI believes that the date marking text for both older infants and young children should be aligned and supports the text proposed for young children be used here.
### 9.5 Information for use

**Colombia** supports proposed text. Numerical 9.5.1. It is proposed to include in the labeling an indication that the product is not sterile.

**Ecuador**

9.5. Ecuador suggests including messages regarding the use of the product, such as:

9.5.1 **[Ready to use] products in liquid form should** may be used [either] directly, or in the case of concentrated liquid products and powdered products, must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. **[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]** Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

We the support removal of the square brackets and the text as it is.

**Ghana**

9.5.1 **[Ready to use] products in liquid form should** may be used [either] directly, or in the case of concentrated liquid products and powdered products, must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, **and maintained at temperature not less than 70 degrees before reconstitution of the product** according to directions for use. **[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]** Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

We support deleting the brackets in the statements in 9.5.1., and 9.5.2.

**India**

This is as per WHO booklet

**Mali**

accepts the text as proposed and the deletion of the brackets.

**Philippines**

HKI supports the text as proposed - deletion of the square brackets, deletion of strikethrough text and additional words.

**IBFAN**
<table>
<thead>
<tr>
<th>Section</th>
<th>Proposal</th>
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<tbody>
<tr>
<td>9.5.5</td>
<td>Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.</td>
</tr>
<tr>
<td>9.5.6</td>
<td>The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition and that older infants should receive complementary foods in addition to the product. Remove brackets.</td>
</tr>
<tr>
<td>9.5.1</td>
<td>[Ready to use] products in liquid form should be used directly, or in the case of concentrated liquid products (and powdered products), must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.</td>
</tr>
<tr>
<td>9.5.2</td>
<td>Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.</td>
</tr>
<tr>
<td>9.5.3</td>
<td>The label shall carry clear graphic instructions illustrating the method of preparation of the product.</td>
</tr>
<tr>
<td>9.5.4</td>
<td>The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.</td>
</tr>
<tr>
<td>9.5.5</td>
<td>Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.</td>
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</tr>
<tr>
<td>9.5.7</td>
<td>Powdered milk products are not sterile and reconstitution, storage and handling instructions should be</td>
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<tr>
<td>Recommendation 10</td>
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<td>-------------------</td>
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<tr>
<td><strong>Additional Labelling Requirements</strong></td>
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<tr>
<td><strong>9.6.1</strong> Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:</td>
<td></td>
</tr>
</tbody>
</table>
| a) the words "important notice" or their equivalent;  
| b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;  
| c) a statement that the product should only be used on advice of an independent health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.  
| d) the statement: "The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding." |
| **9.6.2** The label shall have no pictures of infants and women nor any other picture[,] or text[,] which idealizes the use of follow-up formula. The label shall have no pictures images, text or other representation that might: |
| 9.6.2.1 idealize the used of follow-up formula for older infants;  
| 9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);  
| 9.6.2.3 recommend or promote bottle feeding;  
| 9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;  
| 9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.] |
| **9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used. [[in addition, the product should not be compared to breast-milk].] |
| **9.6.4** Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes[,] and to enable consumers to make a clear distinction between them[,] in particular as to the text, images and colours used.] |

Argentina agrees with the proposed text. In addition, we believe these labelling requirements are more stringent than those for infant formula. Hence, we suggest the Committee considers a further review of the Codex Stan 72 -1981 in the future.

Australia supports the Chair’s view that the standard should be clear and concise, with no duplication and not be more stringent than the Codex Infant Formula Standard labelling provisions. On this basis:
For 9.6.1  a), b) and c) Australia supports the chairs recommendations for the deleted text.  
For 9.6.2  We support deletion. Australia also considers advice from a health worker would include this information.  
For 9.6.4  We note an editorial correction is required in 9.6.2.1 to remove a redundant letter ‘d’ in the word ‘used’.

Australia
### For 9.6.2.5 - We oppose the inclusion of this text because it is inconsistent with the infant formula standard. In addition, we consider there is a lack of clarity on what would be considered an endorsement and we are unaware of any definition for ‘endorsement’ in Codex labelling texts.

For 9.6.3 - We support the deletion of the text in square brackets for consistency with the Codex Infant Formula Standard.

For 9.6.4 – We support the proposed changes within the square brackets, but note an editorial correction is needed to replace a comma after ‘them’ with a full stop.

### 9.6.4

Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

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### Brazil

Brazil supports Recommendation 10 with some amendments.

a) With regard to section 9.6.1 (d), we strongly support that the text should be retained as suggested by the WHO representative in the 37th meeting of CCNFSDU. Moreover, the sentence is in accordance with recommendation 4 of WHA 69.9 - Ending inappropriate promotion of foods for infants and young children.

If the Committee considers that the text conflicts with the proposed definition for follow-up formula for older infants, Brazil suggests rewriting the sentence instead of only deleting it. In this sense, it is important to not ignore that in the EWG there was majority support for retaining text within 9.3.1(d) (13 CM, 2 CO).

b) The text of section 9.6.2.4 "nearly" and "that makes a comparison to breast milk" should also be retained for consistency with the text of recommendation 4 of WHA 69.9 which states "21. Messages should not: (…) (2) include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent or superior to breast-milk;". We consider that the sentence is not a duplication with other requirements presented in Additional Labelling Requirements.

In this sense, it is important to consider that although some of the compositional and quality requirements of follow-up formula considers the reference of human milk, it is scientific and technological impossible that an infant follow-up formula reflects all its complexity, safety and health benefits. So, in our opinion, any type of comparison to breast-milk or suggestion presented on label that the product is nearly equivalent or superior to breast-milk is a potentially misleading information to consumer.

Moreover, we would to like to highlight that all the infant follow-up formulas must meet the quality and safety requirements which consider the same parameters based on the breast-milk. So, comparisons to breast-milk should not be permitted, because it would mislead the consumers leading them to believe that one formula is better or safer than others.

c) In relation to the section 9.6.4, we support the maintenance of text in square brackets as it is accordance with recommendation 5 of WHA 69.9:

Recommendation 5. There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children.

(1) The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).

In this matter, Brazil considers that if the Committee considers that the text could be misinterpreted, it is more reasonable to rewrite the sentence considering the WHA 69.9 references instead of only deleting it.

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### Canada

Canada
<table>
<thead>
<tr>
<th><strong>product is similar, nearly equivalent to or superior to breast-milk:</strong></th>
<th><strong>Canada generally agrees with this section (9.6). However, Canada suggests a modification to 9.6.2.4 that the phrase “product is equivalent to or superior to breast-milk” is replaced by “product is similar, equivalent or superior to breast-milk”. Canada has observed on the market FUFs for older infants with the following claim ‘closest formula to breastmilk’. Canada prefers inclusion of the word ‘similar’ to reiterate that no such comparisons of FUF to breastmilk should be permitted on the labelling.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colombia supports the text in 9.6.</strong></td>
<td><strong>Colombia</strong></td>
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<tr>
<td>Colombia supports the text in 9.6.2. 9.6.3</td>
<td>We recommend specifying in each food group, the age range for which the product is intended.</td>
</tr>
<tr>
<td>Colombia support the text in 9.6.4</td>
<td><strong>Costa Rica</strong></td>
</tr>
<tr>
<td><strong>Costa Rica notes the discussions in CCNFSDU39 and supports most of the proposed changes. However, as the document prepared by the Chairman of the eWG also indicates that it is possible that changes may need to be made to the provisions in order to ensure that Section 9.6 is not stricter than required with respect to infant formula labelling, it believes that in:</strong></td>
<td><strong>Cote d'Ivoire</strong></td>
</tr>
<tr>
<td>9.6.1 a) and b): Cote d'Ivoire supports the proposals</td>
<td>Cote d'Ivoire approves the proposals 9.6.2.4: Cote d'Ivoire approves the proposed text but suggests adding the term “almost equivalent”. The text would read as follows: &quot;to compromise or discourage breastfeeding, or to imply that the product is equivalent or almost equivalent, or superior to breast milk&quot;</td>
</tr>
<tr>
<td>9.6.1 c): Cote d'Ivoire supports this proposal with the deletion of the brackets and the strikethrough text</td>
<td>9.6.2: Cote d'Ivoire does not approve the text as drafted and proposes adding the category 6-12 months (older infants). The text will therefore read as follows: &quot;The label must not include any photographs of infants, older infants and women - or any other images, text or representations likely: ...&quot;. This addition is necessary because the purpose of the text is to avoid idealising the use of the product by showing images of children for whom the product is intended and young children for whom the product is inappropriate. 9.6.2.1. 9.6.2.2 and 9.6.2.3: Cote d'Ivoire approves the proposals 9.6.2.4: Cote d'Ivoire approves the proposed text but suggests adding the term “almost equivalent”. The text would read as follows: &quot;to compromise or discourage breastfeeding, or to imply that the product is equivalent or almost equivalent, or superior to breast milk&quot;</td>
</tr>
<tr>
<td>9.6.2 4: Cote d'Ivoire approves the proposed text but suggests adding the term &quot;almost equivalent&quot;. The text would read as follows: &quot;to compromise or discourage breastfeeding, or to imply that the product is equivalent or almost equivalent, or superior to breast milk&quot;</td>
<td>9.6.2.1, 9.6.2.2 and 9.6.2.3: Cote d'Ivoire approves the proposals 9.6.2: Cote d'Ivoire does not approve the text as drafted and proposes adding the category 6-12 months (older infants). The text will therefore read as follows: &quot;The label must not include any photographs of infants, older infants and women - or any other images, text or representations likely: ...&quot;. This addition is necessary because the purpose of the text is to avoid idealising the use of the product by showing images of children for whom the product is intended and young children for whom the product is inappropriate. 9.6.2.1. 9.6.2.2 and 9.6.2.3: Cote d'Ivoire approves the proposals 9.6.2.4: Cote d'Ivoire approves the proposed text but suggests adding the term “almost equivalent”. The text would read as follows: &quot;to compromise or discourage breastfeeding, or to imply that the product is equivalent or almost equivalent, or superior to breast milk&quot;</td>
</tr>
<tr>
<td><strong>9.6.1</strong>: Labels should not discourage breastfeeding. Each label on the container shall bear a clear, prominent and easily readable indication, including the following points:</td>
<td>9.6.1 a) and b): Cote d'Ivoire supports the proposals 9.6.1 c): Cote d'Ivoire supports this proposal with the deletion of the brackets and the strikethrough text 9.6.1 d): Cote d'Ivoire is in favour of deleting point d because it does not consider it necessary</td>
</tr>
</tbody>
</table>
| Ecuador | 9.6.1 Ecuador believes that it could be simplified into a single compulsory message instead of including a series of points, some of which may result in an ambiguous interpretation. We recommend: “IMPORTANT NOTICE: Breast milk is the best food for the health and nutrition of your infant and young child because it is the only complete and irreplaceable food. The use of this product is only recommended in the following cases: the absence of the mother and infant metabolic disorders (galactosemia, phenylketonuria, maple syrup urine disease, diseases transmitted through breast milk). This product should only be used on the advice of a health professional.

9.6.2 Ecuador believes it is important to add the term “older infants” more than the terms “infants” and “women”, as this is the term used throughout most of the document. In addition, the phrase “that idealises the use of complementary formulas” should be eliminated given what is described in 9.6.2.1.

9.6.2.5 Ecuador does not agree with the text and believes the following option is more appropriate: “have the approval or any other type of endorsement that may be interpreted as such, including approvals provided by a professional, individual, group or organisation, unless specifically approved by the relevant national regulatory authority”.

9.6.4 Ecuador does not agree with the text. It believes it is important for the text to indicate the following: “The products will be labelled to avoid any risk of confusion between infant formulas, complementary formulas for older infants, [product name] for young children and formulas for special medical uses by means of the use of different colours, schemes, designs and names, not including the name of the company and its logo. The
c) a statement that the product should only be used on advice of an independent health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.

9.6.2.4 Egypt supports the text to be as follow:
"undermined or discourage breastfeeding or suggests that the product is nearly equivalent to or superior to breast-milk"

The EU, in general, agrees with the recommendation proposed by the Chairs which aims at ensuring that the labelling of Follow-Up Formula for older infants does not discourage breastfeeding. This principle is also reflected in a number of provisions of EU legislation as for example in Article 10 of Regulation (EU) No 609/2013, Article 6(6) of delegated Regulation (EU) 2016/127 which apply to follow-on formula and are very similar (if not identical in certain cases) to those listed in Article 9.6 of the Infant Formula Standard.

We support the provisions of this section as they conform with the International Code of Marketing of Breastmilk substitutes.

9.6.1 The products covered by this standard are breast-milk substitutes and shall be presented as such. Marketing of such products should confirm to provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions.

c) a statement that the product should only be used on advice of an independent health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.

d) the statement: "The use of this product must not replace breast milk and lead to cessation of continued breastfeeding."

9e) [These products are breast milk substitutes and should be represented as such. Marketing of these products needs to be regulated as per the provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions.]

9.6.4 Products shall not be cross branded with infant formula or be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

9.6.5 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);

cross-linked promotion of products is not permitted.

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<table>
<thead>
<tr>
<th>Country</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Egypt</td>
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<td>EU</td>
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<td>Ghana</td>
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<tr>
<td>India</td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td></td>
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</tbody>
</table>

Indonesia supports the deletion of section 9.6.1 (e) and supports the text in 9.6.2

Indonesia proposes to delete section 9.6.2.2

Indonesia supports the proposed text in 9.6.2.5. It should be noted that the Codex Stan 72-1981 does not cover this provision.
c) a statement that the product should only be used on the advice and direction of an independent health worker as to the need for its use, [including any exception to the age of introduction of 6 months], and the proper method of its use.

[9.6.2] The label shall have no pictures of infants, young children, and women nor any other picture[,] or text[,] which idealizes the use of follow-up formula. The label shall have no pictures images, text or other representation that might:

9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggest makes any reference to equivalence or superiority of the product to breast-milk;

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, including individuals, unless this has been specifically approved by relevant national, regional or international regulatory authorities and endorsed by such regulators.

Jamaica

Mali accepts the text as proposed.
But for 9.6.2 Mali supports the addition of the term "older infant"; the sentence will read as follows: the label should not have any images of infants, older infants or women.

9.6.3

b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;

9.6.2 Nepal reiterates that the term "older infants" must be added in the first sentence after infants, as this product is certainly designed for older infants.

9.6.2.4 Nepal has been proposing in the consultation paper that these products should not be compared to breastmilk, and labelling should not provide any mis-information regarding these products equivalence to breastmilk. Thus Nepal strongly proposes not to delete the words "that makes a comparison to breast-milk", and add the word "nearly equivalent to" before "equivalent to" in the sentence.

9.6.2.5 propose to delete the words "regional or international"

9.6.4 Nepal proposes to include the deleted sentence

New Zealand

NZ comment on recommendation 10:
9.6.1  Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
   a) the words "important notice" or their equivalent;
   b) the statement “Breast-milk is the best food for your baby” or a similar statement as to the superiority of breastfeeding or breast-milk;
   c) a statement that the product should only be used on advice of an health worker as to the need for its use and the proper method of use.

9.6.2  The label shall have no pictures of infants and women nor any other picture text, or representation that might:
   9.6.2.1  idealize the used of follow-up formula for older infants;
   9.6.2.2  suggest use for infants under the age of 6 months (including references to milestones and stages);
   9.6.2.3  recommend or promote bottle feeding;
   9.6.2.4  undermine or discourage breastfeeding, or suggests that the product is equivalent to or superior to breast-milk;
   9.6.2.5  convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless [use of this endorsement] this has been specifically approved by relevant national, regional or international regulatory authorities.

9.6.3  The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4  Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them.

Whilst New Zealand supports an approach to 'Additional Labelling Requirements' for follow-up formula for older infants that is not more stringent than what is required on the label of infant formula, we note that whilst a similar provision to 9.6.2.5 is not included within the Infant Formula Standard, there is emerging consumer interest in this area (by way of example; endorsement or identification of food as “Halal”, ‘Kosher’ or ‘organically grown’). Whilst not referenced in the Introductory Paragraph to the Labelling Section, the Codex General Guidelines on Claims (CAC/GL 1-1979) provide guidance on the use of certain terms such as ‘natural’, ‘organically grown’, and state that such terms should be ‘in accordance with the national practices in the country where the food is sold’ and ‘the use of these terms should be consistent with the prohibitions set out in Section 3’ (of the Guidelines). Furthermore, Codex has General Guidelines for the Use of the Term “Halal” (CAC/GL 24-1997) and the Guidelines on Claims allow for statements on the religious or ritual preparation of a food, ‘provided that the food conforms to the requirements of the appropriate religious or ritual authorities’.

We are therefore open to further discussion on the wording of provision 9.6.2.5 as we would not want to present a statement which is in direct conflict with other Codex permissions such as those discussed above. We therefore present the following modified draft text as a starting point for this discussion:

9.6.2.5  convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless [use of this endorsement] this has been specifically approved by relevant national, regional or international regulatory authorities.

We support the proposed amendments to 9.6.1, including the deletion of the text contained within the [ ] for c). The text with strikethrough within 9.6.1 c) is in conflict with 9.6.2.2 and hence our support for its deletion.

New Zealand supports labelling which does not discourage breastfeeding and notes that this approach is already covered at the beginning of provision 9.6.1 and therefore supports the deletion of 9.6.1 d).

With respect to provision 9.6.2, we support the proposed changes including those presented for 9.6.2.4. We support 9.6.3 and the proposed deletion of the text in [ ].

In relation to 9.6.4, New Zealand supports deletion of ‘...in particular as to the text, images and colours used’. It is our view that adequate labelling provisions regarding age and the intended consumer are already proposed and we do not believe that this...
c) a statement that the product should only be used on advice of an independent health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.

9.6.2
9.6.3

We support retention of the bracketed statements except Section 9.6.1 letter [d) the statement; “The use of this product must not replace breast-milk”. This statement should be deleted since it is contradictory to the nature of this product for older infants which can be sold and marketed as a breast milk substitute worldwide.

b) the statement “Breast-milk is the best food for your baby up to two years old or beyond” or a similar statement as to the superiority of breastfeeding or breast-milk;

c) a statement that the product should only be used on advice of an independent health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]

9.6.4 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes[ and to enable consumers to make a clear distinction between them. in particular as to the text, images and colours used.]]

[9.6.2 The label must not include images of infants aged between 0 and 12 months or women, or any other image[,] or text[,] idealising the use of the follow-on formula. The label must not include any image, text or other representation likely:

9.6.2.4 to compromise or discourage breastfeeding, which makes a comparison with breast milk or to suggest that the product is of almost equivalent quality, almost equivalent quality or higher quality than breast milk:]

statement adds any value or further guidance in this regard.

Norway
We consider it important to retain that health workers should be independent, to ensure they are without any conflict of interests. Furthermore, the text is consistent with the Infant Formula Standard where term “independent health worker” is used. We believe it would be confusing requiring independent health workers for infant formula, while not doing it for follow-up formula for older infants and young children.
We support the deletion of the statement “including any exception to the age of introduction of 6 months”
We are in favour of the proposal.
We agree with the proposal.

Philippines
The Philippines proposes to revise Statement 9.6.1b by adding “up to two years old and beyond” since this is compliant to the International Code of Marketing Breastmilk Substitute.
We are of the opinion that the use of the term “independent” should be retained in Statement 9.6.1c since it is consistent with the Codex Standard for Infant Formula and Formula for Foods for Special Medical Purposes Intended for Infants. The word “independent” can be retained to ensure that the health worker is not affiliated to any companies which may have conflict of interest in advising primary caregivers on what brand to choose given the availability of several follow up formula products in the market.
The rest of the bracketed statements are in compliance with the International Code of Marketing Breastmilk Substitutes except bracketed texts in 9.6.1c and 9.6.4. We propose to delete “except any exception to the age of introduction of 6 months since it creates opportunities for inappropriate promotion of the product for use below 6 months of age.
The Philippines is in agreement with Statements 9.6.2.1-9.6.2.4. However we propose to delete “unless this has been specifically approved by relevant national or regional regulatory authorities” since this may open allowance for endorsement that may undermine breast milk or the practice of breastfeeding.
We also recommend to delete the phrase “as to the text, images and colours used” in Statement 9.6.4 since these could be considered as trade barriers.

Senegal
Recommendation 10
Position:
9.6.1 a) : Senegal supports this proposal
9.6.1 b): Senegal supports the text as proposed
9.6.2.5 to declare or imply that the product is approved by a professional or other body, unless specifically approved by appropriate national and, if necessary, regional or international regulatory authorities.

9.6.2: Senegal does not support the text as drafted and proposes adding the category 6-12 months (older infants). The text will therefore read as follows: “The label must not include images of infants aged between 0 and 12 months or women, or any other image, text or representation likely...”

9.6.1 d): Senegal supports the deletion of point d because it does not consider it necessary

9.6.2.4: Senegal supports the proposed text but suggests adding the term “almost equivalent”. The text would read as follows: “to compromise or discourage breastfeeding, or to imply that the product is equivalent or almost equivalent, or superior to breast milk”

9.6.2.5: Senegal supports the text on the condition that the words “if necessary, regional or international regulatory authorities” are added. The text should read as follows: “to declare or imply that the product is approved by a professional or other body, unless specifically approved by appropriate national and, if necessary, regional or international regulatory authorities”

9.6.3: Senegal supports the text as proposed

9.6.4: Senegal does not support the text as drafted and suggests the following redraft: “The product shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [product name] for young children, and formula for special medical purposes, and to enable consumers to clearly distinguish between them by means of different texts, images and colours.”

Sri Lanka

The proposed rewording is much clearer and was proposed to the e WG

Switzerland supports in a large part the proposed text [d) the statement; ‘The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding’.]

9.6.2.4: undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk.

Rational

It is well known that breast-milk contain many substances that are
9.6.4. Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

USA

The United States supports Recommendation 10 for the additional labelling requirements for Section 9.6 for follow-up formula for older infants and with acceptance of the deletions of the square brackets and text as well as suggested edit to “c” to clarify that the health care worker is not promoting formula feeding but the child’s caregiver is requesting information regarding feedings appropriate for that infant. We also suggest an edit to 9.6.3 to provide clarity why the terms are inappropriate for use.

c) a statement that the product mother/parent/guardian should only be used on seek the advice of an a health independent health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.

9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages).
9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory
9.6.3 **Packaging**

The terms that describe the product is like human, breast, or mother's milk such as the terms "humanized", "maternalized" or other similar terms shall not be used. In addition, the product should not be compared to breast milk.

**Viet Nam**

9.6 Additional Labelling Requirements

In general VIETNAM agrees to the proposed wording, except 2 suggestions as following:

- 9.6.2.2: to delete the phrase "(including references to milestones and stages)" and replace by "suggest use for infants under the age of 6 months."
- 9.6.2.5: to delete the phrase "(or anything that may be construed as an endorsement)" and replace by "convey an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional authority.

HKI supports the deletion of the square brackets.

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points: "IMPORTANT NOTICE: Breastmilk is best for your baby. Infants should be exclusively breastfed for the first 6 months of life and continue to be breastfed to two years of age or beyond. This product should only be used on the advice of a health care worker.

- a) the words "important notice" or their equivalent;
- b) the statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- c) a statement that the product should only be used on advice of an [independent] health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.
- d) the statement: "The use of this product must not replace breast milk and lead to cessation of continued breastfeeding."

9.6.2 The label shall have no pictures of infants, older infants and women nor any other text, which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might:

- 9.6.2.4 We support the proposed strikethrough text.
- 9.6.2.5 convey an endorsement or anything that may be construed as an endorsement including by a professional, individual, group, or any other body organization, unless this has been specifically approved by the relevant national, regional or international regulatory authorities.

9.6.4 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and breast milk.

HKI supports the deletion of the square brackets.

9.6.1 a) HKI supports the text as proposed.

9.6.1 b) HKI strongly believes the text should read: 'the statement "Breastmilk is the best food for your baby. Infants should be exclusively breastfed for the first 6 months of life and continue to be breastfed to two years of age or beyond." must appear on the label.' HKI strongly believes that there should not be the option for 'or a similar statement as to the superiority of breastfeeding or breast milk', as what is considered similar is subjective and experience shows that the manufacturers of these products water down as much as possible any text that negatively impacts on the products image. Also see comments under 9.6.1 d).

9.6.1 c) HKI supports the text as proposed - deletion of strikethrough text. We point out a grammatical error – the word 'an' should be replaced with 'a' i.e. '…used on the advice of a health worker…'

9.6.1 d) HKI supports the deletion of this statement and refers to
formula for older infants, (name of product) for young children, and formula for special medical purposes.

through the use of different color schemes, designs, names, slogans and mascots other than company name and logo. Cross-promotion between products is not permitted, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.]

the comment made by UNICEF in the EWG “These products ARE breastmilk substitutes and will replace the milk part of the child’s diet that should ideally be fulfilled by breastmilk.

HKI strongly supports that the term ‘older infant’ must be added to the opening sentence so that it reads ‘The label shall have no pictures of infants, older infants and women nor any other picture, text or representation that might:..’ This addition is necessary, as the purpose of the text is to prevent idealising the use of the product by showing pictures of children for whom the product is intended and younger children for whom the product is inappropriate, from being shown on the label – in line with the text in Infant Formula Standard. Contrary to the comment by the Chair of the EWG in the report, it is NOT more stringent than the infant formula standard, it is necessary to make the text relevant to the standard / age category under discussion. The infant formula standard only refers to infants as that is the age category for which infant formula is intended and for whom one does not want its use idealised. Therefore, this product must refer to both infants and older infants for whom the product use should not be idealised. HKI supports the deletion of the square brackets and the strikethrough text.

HKI strongly believe the text should read ‘undermine or discourage breastfeeding, or suggests that the product is nearly equivalent, equivalent to or superior to breast-milk;’ We reiterate our comment to the EWG that that it is essential to ensure that all possible messages linked to some/any/total equivalence to breastmilk must be prohibited. We refer to the current practices of the manufactures of these products that continue to use wording that implies some level of equivalence to breastmilk. This text must therefore be complete to ensure NO reference to equivalence or superiority to breastmilk.

HKI does NOT support the text as proposed. HKI reiterates its strong belief, as expressed in the EWG, that it is essential to ensure that NO form of endorsement is permitted where the product is being sold, unless approved by the relevant national authority. HKI believes the current text is open to interpretation regarding who may endorse the product and proposes text whereby all categories of endorsement including by individuals, professionals, groups or organisations are not permitted. We agree that endorsement should be allowed if approved by the relevant national authority in the country where sold. We strongly disagree that regional or international authorities have the right to decide on the endorsement of these products. By allowing for regional and international endorsement authority, this text would undermine Member States authority to protect the health of their
9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding.

Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;

c) a statement that the product should only be used on advice of an independent health worker as to the need for its use including that the product is not suitable for infants under the age of six months and the proper method of use.

(d) the statement; 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'.

9.6.2 Remove brackets. The label shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of follow-up formula for older infants.

Or other representation that might:

9.6.2.1 idealize the used of follow-up formula for older infants;

9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);

9.6.2.3 recommend or promote bottle feeding;

9.6.2.4 undermine or discourage breastfeeding, or suggests that the product is equivalent to or superior to breast-milk;

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional, individual, group or organisation, unless specifically approved by the relevant national regulatory authority.

HKI supports the text as proposed – deletion of the strikethrough text.

HKI strongly believes the text should read 'Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, through the use of different colour schemes, designs, names, slogans and mascots other than company name and logo. Cross promotion between products is not permitted.' This statement gives complete clarity as to what is permitted and not permitted and is in line with the WHO Guidance on ending the inappropriate promotion of foods for infants and young children.
formula for older infants, name of product for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images, names, slogans, colours and mascots used.

9.6 ISDI takes note of the discussions at CCNFSDU39 and supports most of the proposed wording.

9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages) months;

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

ISDI strongly opposes the following requirements:

- 9.6.2.2: the phrase "(including references to milestones and stages)" should be deleted

- 9.6.2.5: the phrase "(or anything that may be construed as an endorsement)" should be deleted

The paper prepared the eWG Chair further noted that some modifications to the provisions may be required to ensure that Section 9.6 should not be more stringent than that required on the label of infant formula.

ISDI is of the opinion that the above modifications address this point.

ISDI strongly opposes the following requirements:

- 9.6.2.5: the phrase "(or anything that may be construed as an endorsement)" should be deleted

The paper prepared the eWG Chair further noted that some modifications to the provisions may be required to ensure that Section 9.6 should not be more stringent than that required on the label of infant formula.

ISDI is of the opinion that the above modifications address this point.

The square brackets should be deleted.

c) a statement that the product should only be used on advice of an [independent] health worker as to the need for its use [including any exception to the age of introduction of 6 months] and the proper method of use.

[d) the statement, 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'.

[9.6.2] The label shall have no pictures of infants and women nor any other picture[,] or text[,] which idealizes the use of follow-up formula. The label shall have no pictures images, text or other representation that might:

9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;

9.6.2.5 The words "regional" and "international" should thus be deleted.

9.6.3

9.6.4 Products shall be labelled in such a way as to avoid any risk of cross promotion or confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes[, and to enable consumers to make a clear distinction between them, in particular as to the text images and colours used, in particular as to the text, images and colours used].

UNICEF

Agree to deletion since, as previously explained, these products ARE breastmilk substitutes and will replace the milk part of the child’s diet that should ideally be fulfilled by breastmilk.

Agreed with the reinsertion of the word “independent” and the deletion of the words “including any exception to the age of introduction of 6 months”.

Agree to deletion since, as previously explained, these products ARE breastmilk substitutes and will replace the milk part of the child’s diet that should ideally be fulfilled by breastmilk.

Agreed with the deletion of the square brackets and the strikethrough text.

The strikethrough text should be retained throughout this sub-clause as manufacturers continuously make comparisons to breastmilk, with caregivers being led to believe that although breastfeeding is the gold standard, using these substitutes is almost as good, or not very different from mother’s milk.

Comparisons of any sort should not be allowed.

Following an examination of views expressed in the EWG, UNICEF better understands the risks of sanctioning regional or international approval of endorsement by a professional or other body of the products under discussion. This could undermine...
national sovereignty in the matter and the responsibilities of states to protect the best interests of their mothers and children. Agreed with deletion of the strikethrough text. Agreed with the insertion of the words “cross promotion or” between the words “of” and “confusion” in the first line of this sub-clause. The square brackets should be deleted and the strikethrough text reinstated. The need to avoid cross promotion is emphasized in the 2016 WHO Guidance on ending the inappropriate promotion of foods for infants and young children, which the World Health Assembly has called on Governments to implement.

<table>
<thead>
<tr>
<th>SPECIFIC COMMENTS</th>
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<tr>
<td>SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN</td>
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<tr>
<th>[NAME OF PRODUCT]</th>
<th>[FOLLOW-UP FORMULA] FOR YOUNG CHILDREN</th>
<th>[NAME OF PRODUCT]</th>
<th>FORMULA</th>
<th>FOR YOUNG CHILDREN</th>
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<tbody>
<tr>
<td>INDIA</td>
<td>INDONESIA</td>
<td>MALAYSIA</td>
<td>USA</td>
<td>HKI</td>
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</table>

Malaysia would like to propose the name for product for young children as follows:

- Formulated milk-based (or soy-based) product for young children

Malaysia’s proposal for the changes are for the following reasons:

- the word “formulated” is preferred as it denotes a product that has been prepared with nutritional needs of the young children in mind;
- the word “soy” specifically instead of the general term “plant-based” may be misused and some plant-based products of poor nutritional quality may be used to formulate the product.
- the word “product” is preferred as the term “drink/beverage” has the connotation of general beverages of any nutritional quality

The United States supports Recommendation 18 for further discussion on the Name of Product (for young children) as the current name is not sufficiently descriptive but supports the use of ‘formulated’ within this name.

HKI notes that this issue has not been put forward in the document under discussion but has been under discussion within the EWG and needs to be discussed at the 2018 meeting. The report of the EWG suggests [Formulated] drink for young children.

HKI strongly opposes the use of the word formulated in the name of this product and does not believe there has been sufficient discussion or consensus to include the word in the Standard and that other options must be open for discussion at the 2018.
CCNFSDU meeting.

Justification:
1. WHA 69.9 was adopted by consensus and specifically urged 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 in particular implementation of the guidance recommendations…”. Further WHA 69.9 “calls upon manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion as set forth in the guidance”

Recommendation 2 in the Guidance states that these products are breast-milk substitutes and fall under the International Code of Marketing of Breast-milk Substitutes, which prohibits any promotion and idealisation of these products. Governments and companies are obliged to implement the Guidance and thus the word formulated must be removed from the name of the product as it makes the product sound different to any other milk, fortified milk or breastmilk.

2. HKI is of the opinion, that adding the word ‘formulated’ to the name of the product contradicts the decision by the Committee not to refer to the products as ‘specially’ manufactured. It is our understanding that this deletion was due to the fact that the Committee agreed that the word added no value and all commercially produced foods were specially manufactured. The same applies to formulated. An extensive review of the definitions of the word formulate (the verb for which formulated is the past participle) shows it to mean ‘create or prepare methodically’; ‘to develop a formula for the preparation of’; ‘prepare according to a formula’; ‘to develop all the details of a plan for doing something’; ‘invent it, thinking about the details carefully’. Thus, indeed all commercially produced foods are formulated, and the adjective adds no value to the name of the product unless it is being included to imply some benefit, which HKI strongly objects to and for which we believe there is no justification.

3. HKI has continually raised the concern and strongly believes, that the name given to this product must be neutral and contain no implied benefit/claim. It has globally been agreed that these products are not necessary. These products should therefore in no way be idealised. There is therefore no need to include any adjective in the name of the product.

The use of the proposed adjective ‘formulated’ could be interpreted as indicating a benefit and we strongly oppose this as being potentially misleading. The introductory text makes direct reference to the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) which applies to this product. This Guideline
explicitly prohibits use of nutrition and health claims for foods for infants and young children, except where specifically provided for in relevant Codex Standards or national legislation. HKI accepted this introductory text on the grounds that currently none of the relevant Codex standards allow for claims on these products. Thus, only national legislation can allow for any nutrition and health claims. We support this and strongly believe that only national governments should have the authority to decide if any nutrition or health claim is relevant in their national context. HKI believes allowing for an adjective that is in fact a claim to be used in the name of a product will be setting a very dangerous precedent and must not be permitted.

4. The word ‘formulated’ is very similar to the word ‘formula’ and mothers/caregivers could misinterpret the word or link it to ‘formula’ or ‘follow up formula’ and this is problematic and could result in severe negative nutritional consequences as its composition is not suitable to satisfy the nutritional requirements of a younger child. HKI is aware that in some countries, including the United Kingdom, breast-milk substitutes are referred to as ‘formula milk’. Thus, the use of the word ‘formulated’ for the name of this product could lead to confusion. Research demonstrates that mothers/caregivers misinterpret the names of these types of products and incorrectly feed them to children of an inappropriate age. Research shows that mothers have even misinterpreted the term ‘Follow-up Formula’ in both high-income and low-income settings. In the United Kingdom, 16% of mothers in a 2010 national infant feeding survey reported that they first used follow-up formula before 6 months of age. Among mothers who had never worked, 26% reported that they used baby follow-up formula before 6 months of age (Infant Feeding Survey 2010). One-third (32%) of mothers reported they did not know the difference between various breast-milk substitutes, and health workers were unable to differentiate them as well (Crawley and Westfield, 2016, Infant Milks in the UK: A Practical Guide for Health Professionals – February 2016). In Senegal, nearly 10% of mothers of infants and children under 2 years of age were unable to state what stage of formula they gave their infants (ARCH research, 2016, unpublished analyses). Other research by Cattaneo et al. has also shown that confusion exists among these different products by mothers because of how these products are labelled, clearly indicating the need for Codex to address this critical issue to protect infant older infant and young child health.

In a study in Italy, Cattaneo et al. found that only 43% of mothers could correctly identify the age of use of the products following
As reported by Watson and Heath (2013), the role and use of fortified milk-based products in the diets of older infants and young children, MPI Technical Paper No: 2013/40, New Zealand, “recommendations for the minimum age of follow-up formula introduction are not always followed. France, Ireland, Luxembourg, and the United Kingdom all reported introduction earlier than their country's recommendation, as did Ghana and the Philippines. There is a large range in the age at which follow-up formula is first introduced. The earliest follow-up formula introduction reported was at 1 month by 2% of children in a United Kingdom study of 9,416 mothers. Even within countries there is a range of ages at which follow-up formula is introduced, such as in Sweden, where 44% of children were introduced to follow-up formula at less than 4 months of age, 30.5% between 4 and 6 months of age. Rates of follow-up formula consumption at or before 6 months of age were reported by eight high-income countries and three low- and middle-income countries.

If the [Name of product] for young children is the only product fed to an infant less than 6 months of age, nutritional deficiencies would most definitely result as its proposed composition requires only 50% of the nutrients. HKI believes this may be possible and should be avoided. HKI feels strongly that the word formulated must be removed from the name and that this being presented as the only name for consideration does not reflect feedback from the earlier EWG consultations. HKI recommends the name 'Drink for young children'.

ISDI supports the wording “formulated” in the name of the product as it clarifies that the product is the result of specific and voluntary effort of the manufacturer to prepare a product for a specific intended use. Formulation refers to the phase of theoretical development of the product preceding the manufacturing itself (e.g. choice of specific ingredients when developing the product recipe).

**Recommendations 4, 5, 6**

**[SCOPE]**

1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for [name of product] for young children.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as [name of product] for young children.

<table>
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<th>Australia</th>
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<tr>
<td>For recommendations 4, 5 and 6 Australia supports the text</td>
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<td>Country</td>
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<td>India</td>
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*Only products meeting the criteria set out in the provisions of this section of this standard [should be / are] presented as follow-up formulas for older infants.*
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<tr>
<th>Section</th>
<th>Country</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>1.3</td>
<td>Indonesia</td>
<td>Supports the proposed text and proposes to open square brackets (1.1, 1.2 and 1.3)</td>
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<tr>
<td>1.3</td>
<td>Mali</td>
<td>Accepts the text as proposed and approves the deletion of “should be” and the use of “are”.</td>
</tr>
<tr>
<td>1.3</td>
<td>New Zealand</td>
<td>Agreement on Sections 1.1, 1.2 and 1.3 of the Scope for [name of product] for young children.</td>
</tr>
<tr>
<td>1.3</td>
<td>Philippines</td>
<td>Support statements 1.1-1.3 under Scope and prefer to use the word “shall” in 1.3.</td>
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<tr>
<td>1.3</td>
<td>Senegal</td>
<td>Approves this proposal, the text as proposed, with the deletion of the brackets and the words “should be”.</td>
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<td></td>
<td>Switzerland</td>
<td>Agreement on Sections 1.1, 1.2 and 1.3.</td>
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<tr>
<td>Switzerland supports recommendations 4, 5 and 6</td>
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<tr>
<td><strong>USA</strong></td>
<td>The United States supports Recommendation 4 for Section 1.1 of the Scope for [name of product] for young children as stated. The United States supports Recommendation 5 for Section 1.2 of the Scope for [name of product] for young children with removal of the square brackets and retaining labeling and analytical recommendations. (1.2) The United States supports Recommendation 6 for Section 1.3 of the Scope for [name of product] for young children as stated.</td>
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<tr>
<td><strong>EU Specialty Food Ingredients</strong></td>
<td>As analytical requirements are not specifically covered, EU Specialty Food Ingredients believes they should be removed.</td>
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<tr>
<td><strong>HKI</strong></td>
<td>HKI supports the text as proposed in Sections 1.1, 1.2 and 1.3.</td>
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<td><strong>IBFAN</strong></td>
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<tr>
<td><strong>ISDI</strong></td>
<td>ISDI supports this recommendation for Section 1.1 ISDI supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants. ISDI supports this recommendation for Section 1.3 and favours the word “shall” instead of “should” as this is more consistent with the terminology used in the labelling section of the Standard.</td>
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<tr>
<td><strong>UNICEF</strong></td>
<td>Remove the square brackets. Agreed with deletion of square brackets in 1.2. Agreed with deletion of square brackets and strikethrough text.</td>
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</tbody>
</table>

**This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for [name of product] for young children.**

**1 SCOPE Remove brackets**

1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, use labelling and analytical requirements for [name of product] for young children.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as [name of product] for young children.

1.4 The application of this section of the Standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), 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 the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).
## 2 DESCRIPTION

### 2.1 Product Definition

#### 2.1.1 [Name of product] for young children

Means a product **specially formulated and manufactured** for use **as a breast-milk substitute**, as a liquid part of the **progressively diversified** diet of young children **in order to contribute to the nutritional needs of young children** **when nutrient intakes may not be adequate to meet nutritional requirements**. (Recommendation 8)

#### 2.1.2 [Name of product] for young children

[Follow-up formula] is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

### 2.2 Other Definitions

#### 2.2.1 The term **young child**

Means a person from the age of more than 12 months up to the age of three years (36 months).

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**Argentina**

Recommendation 8:

Argentina agrees with the proposed text, even though it remains of the opinion that the word “specially” should be retained, as these products are specially processed or formulated to satisfy particular dietary requirements.

**Australia**

Australia supports the definition with the following amendments to the text in square brackets.

- Inclusion of formulated - Given the proposed name of product (as per recommendation 18) includes ‘formulated’ it may be necessary to also include reference to ‘formulated’ in the definition (subject to discussion and agreement on the proposed name). If this is the case Australia suggests removal of the words ‘and manufactured’ instead.

- We support deletion of the text ‘as a breastmilk substitute’. These products are not intended to be a nutritionally complete product and the composition of the product as agreed to by the Committee does not support this role. In Australia these products for young children are regulated as special dietary use products to be consumed in situations where energy and nutrient intakes are inadequate. We would also like to highlight the conclusion of the 2017 eWG that due to the diet pattern of a young child, [Name of the product] for young children could not be considered as a breast milk substitute.

- We support deletion of the text ‘progressively’ and can support retention of ‘diversified’ as this takes into account the role as described by the 3 principles agreed by the Committee during CCNFSDU38, which position [Name of the product] for young children as a complementary liquid part of the diet of young children.

- Australia considers the sentence ‘in order to contribute to the nutritional needs of young children’ may imply the product would be necessary for meeting the nutritional needs of all young children. Our preference would be to retain the phrase in the last
square bracket [when nutrient intakes may not be adequate to meet nutritional requirements], to more clearly capture the role and purpose of the product. This also aligns with the 3 principles agreed by the Committee for the role of [name of product] for young children.

The principles:

i. Contribution to the nutritional needs of young children where the nutrient is widely inadequate; and/or

ii. Contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or

iii. The nutritional quality and integrity of product to ensure nutritional safety

Brazil

Brazil supports the modified definition for [name of product] for young children presented in Recommendation 8. The essential composition and quality factors established in the proposed standard for this product are not based on human milk. So, it is not correct to state in the definition that the product is formulated and manufactured with this aim.

However, we would like to highlight that the acknowledgment that the [name of product] for young children is not suitable for use as a breast-milk substitute does not imply that the product cannot be presented and/or incorrectly used with this aim.

So, considering that this practice undermines optimal infant and young child feeding, specially the WHO recommendation of exclusive breastfeeding in the first 6 months of life and the continuation of breastfeeding up to 2 years and beyond, we strongly support that CCNFSDU considers in the standard for [name of product] for young children all relevant WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes, the WHA69.9 and the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children.

Canada

Canada generally agrees with recommendation except for one point.

Canada has concerns with the chair’s proposal to choose “in order to contribute to the nutritional needs of young children”. Canada does not support this phrase as it implies that these products are necessary when it has been agreed by the committee that these products are not. Canada suggests that the use of the second phrase is more appropriate: “when nutrient intakes may not be adequate to meet nutritional requirements”
**Complementary formulas for older infants** are understood as all products *specially* manufactured to be used as *breast-milk substitutes*, as the liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.

<table>
<thead>
<tr>
<th>Country</th>
<th>Comments</th>
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</table>
| Colombia      | 2.1.2 supports proposed text  
Other definitions supports proposed text                                                                                                                                                                                                                                                                 |
| Costa Rica    | Costa Rica supports the definition as proposed by the Chairman of the eWG, but retaining the word “specially”. It supports the phrase “as breast-milk substitute”, for the same reasons as the above recommendation. With respect to the phrase “[for the purpose of contributing to the nutritional needs of small children]”, the text should be amended to avoid the repetition “of small children”. It should read: “for the purpose of contributing to nutritional needs”. Although the product, according to the standard, is nutritionally equivalent to breast milk, Costa Rica, as indicated during the consultations of the Electronic Working Group, supports the definition retaining the word “specially” and eliminating the phrase “as a breast-milk substitute”. The term “specially” has been utilised in the wording of various Codex standards, such as Codex STAN 146-1985, Codex STAN 72-1981, Rev. 2007 y CAC / GL 8-1991, Rev. 2013) related to foods for infants and young children that affirm that these products are “specially manufactured/formulated”. The Standard for Infant Formulas (CX STAN 72-1981) defines infant formula as a breast-milk substitute and affirms that "No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life". Follow-on formulas are manufactured specially for use as the liquid part of a progressively diversified diet for older infants. These products do not, by themselves, satisfy the nutritional requirements of older infants. As such, it is potentially misleading to affirm that they may be used as a substitute for breast milk or as a replacement for infant formula. |
| Cote d’Ivoire | Cote d’Ivoire does not support the text as proposed and proposes retaining the phrase "as a substitute for breast milk" in the definition. The definition should read as follows: [Product name] for young children means a product designed to be used as a substitute for breast milk, as a liquid part of a diversified diet for young children to contribute to the nutritional needs of young children. |
| Ecuador       | 2.1.1 Ecuador believes the definition should be as follows: “The name of the product for small children is understood to refer to all
manufactured products to be used as a breast-milk substitute as the liquid part of a progressively diversified diet for older infants”. As the International Code of Marketing of Breast-Milk Substitutes defines a breast-milk substitute as “any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose”. The Code does not provide a maximum age for the use of a substitute and the Global Strategy for Infant and Young Child Feeding adopted by the World Health Assembly recommends that breastfeeding continue until two years of age or more. In addition, the Code provides a clear distinction between foods that serve as a substitute for breast milk and those that complement breast milk (if they do not satisfy the child’s nutritional requirements).

<table>
<thead>
<tr>
<th>EU</th>
<th>The EU strongly supports the Chairs’ proposal to remove the reference to breast-milk substitutes from the definition, taking into account that different views exist on what a breast milk substitute is. It must be acknowledged that it is difficult to anticipate how Follow-Up Formula is consumed, namely whether it will replace, or integrate breast milk in the diet of infants and young children. The whole issue is even more complicated for [Name of Product] for young children, taking into account that after one year of life, cow’s milk consumption is also recommended in the diet and the product can also replace/integrate cow’s milk consumption. The EU does not support the inclusion of the text “in order to contribute to the nutritional needs of young children” taking into account that Follow-up formula for older infants and [Name of product] for young children can be considered as conceptually similar (i.e. they are liquid elements in the diversified diet of older infants and young children,) and that this element is not present in the definition of Follow-Up Formula for older infants. The EU would therefore support the following definition: [Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children.</th>
</tr>
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<tbody>
<tr>
<td>Ghana</td>
<td>We support the proposed product definition</td>
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<tr>
<td>India</td>
<td></td>
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<tr>
<td>Indonesia</td>
<td>Indonesia supports the proposed text and proposes to open square brackets</td>
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<tr>
<td>Jamaica</td>
<td></td>
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<td><strong>Country</strong></td>
<td><strong>Comment</strong></td>
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<tr>
<td><strong>Malaysia</strong></td>
<td>Malaysia agrees with the proposed statement in square bracket [in order to contribute to the nutritional needs of young children]. Malaysia is of the opinion that the word “progressively” should be retained in the definition for [Name of product] for young children which young children generally eat family foods, while milk is a wholesome addition to the child’s regular diet.</td>
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<td><strong>Mali</strong></td>
<td>Mali does not approve the text and strongly supports the use of the phrase “substitute for breast milk”.</td>
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<td><strong>Nepal</strong></td>
<td>Nepal reiterates the fact that [name of product] for young children are also breastmilk substitutes, and thus [as a breastmilk substitute] should not be deleted. These products are consumed by children above 1 years of age, and which is still a breastfeeding period, as recommended by WHO and other international IYCF guidelines. WHA 69.9 guidance was endorsed by Nepal, which clearly urges its member states to “take all necessary measures” for the implementation of the guidance. Thus, Nepal strongly opposes the deletion of the words “as a breastmilk substitute” and therefore, the product should be defined as a breastmilk substitute.</td>
</tr>
<tr>
<td><strong>New Zealand</strong></td>
<td>Recommendation 8: New Zealand does not support defining [name of product] for young children as a breast-milk substitute. The role and purpose of these products in the diets of young children, and the nutritional composition of these products makes them unsuitable and unsafe to be considered a breast-milk substitute. For this reason New Zealand considers it important that the definition of these products include the role in the diet. If the role of the product is not included within the definition, the definition could be taken to include any beverage for this age group. At CCNFSDU38 the Committee agreed to three principles to help guide the composition of these products. The first principle was; contribution to the nutritional needs of young children where the nutrient is widely inadequate. New Zealand therefore supports inclusion of the text in order to contribute to the nutritional needs of young children to ensure the role and purpose of these products is captured within the definition. We have suggested</td>
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<tr>
<td>Statement</td>
<td>Position</td>
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<tr>
<td><strong>2.1.1</strong> [Name of product] for young children means a product specially [formulated and] manufactured for use as a breast-milk substitute, as a liquid part of the progressively diversified diet of young children [in order to contribute to the nutritional needs of young children] when nutrient intakes may not be adequate to meet nutritional requirements.</td>
<td>Philippines</td>
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<td>Senegal</td>
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<td>HKI</td>
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feeding is to practice exclusive breastfeeding from birth to 6 months of age and introduce complementary foods at 6 months of age (180 days) while continuing to breastfeed until 2 years of age or beyond. WHA 54.2 also called on governments to strengthen activities to protect, promote and support these practices and lead communities to adhere to them. Thus, any product used towards the liquid part of the diversified diet will displace breastmilk, especially when the product is a milk type product (whether from animal or plant origin) and this must be made clear in the definition.

The definition should be clear as to the function of the product and this is only partially covered if the text does not say ‘as a substitute for breastmilk’. Functionally, any milk product for older infants and young children 6 to 36 months of age may be used with other foods, displacing rather than complementing the intake of breastmilk. They are thus ipso facto breast-milk substitutes, and this must be made clear in reading the Standard and the inclusion of the words ‘as a breast-milk substitute’ is therefore essential. There can be no lack of clarity in the definition that could cause any misinterpretation or confusion.

2. WHA 69.9 was adopted by consensus at the World Health Assembly in 2016 and specifically urged 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 in particular implementation of the guidance recommendations…”. Further WHA 69.9 “calls upon manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion as set forth in the guidance.”

Recommendation 2 of the Guidance clearly states that these products are breast-milk substitutes. For this reason, and to ensure the implementation of the guidance as per WHA 69.9 that both governments and companies are obliged to implement, the definition should be explicit that these are breast-milk substitutes. The guidance does not differentiate between these products and follow-up formula for older infants and neither should Codex.

3. The International Code of Marketing of Breast-milk Substitutes (1981) defines a breast-milk substitute as “…any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose.” It does not provide an upper age limit for the definition of a breast-milk substitute and the Global Strategy for Infant and Young Child Feeding adopted by the World Health Assembly (2003) recommends breastfeeding continue for 2 years or beyond. Furthermore, the Code makes a clear distinction between foods
that ‘replace’ breast-milk (and are thereby breast-milk substitutes) and those that ‘complement’ breast milk when it no longer satisfies infant nutritional requirements. Thus, distinguishing between a breast-milk substitute and a complementary food depends on whether the food directly reduces breast-milk consumption or adds to it.

The WHO Scientific Advisory Group, which developed the recommendations that underpin the WHO Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children (2016) concluded that there was sufficient evidence that milks targeted specifically to children under 3 years of age do replace the intake of breast milk.

The WHO note “Information concerning the use and marketing of follow-up formula” (2013) states that “…follow-up formula is not a suitable substitute for breast milk due to its content.” Not a suitable substitute for breast milk is not the same as a breast-milk substitute. In the current draft of the review of the Follow-up Formula Standard, neither the formula for older infants (6-12 months) and [Name of product] for young children (12-36 months) are nutritionally suitable as a sole source of nutrition. They are, however, breast-milk substitutes. Definitions of infant formula and complementary feeding by Codex Alimentarius, the European Food Safety Authority and the United States are consistent with this interpretation.

- The Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72 – 1981) defines infant formula as “… 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.” This definition clarifies that a breast-milk substitute includes - but is not limited to - infant formula. Otherwise, the term “breast-milk substitute” would not have been included in the definition. http://www.fao.org/fao-codexalimentarius/[...].pdf

- The European Food Safety Authority (EFSA) (2009) in its definition of complementary feeding clarifies that a breast-milk substitute includes products not designed to be a sole source of nutrition for an infant. It defines complementary feeding as “…the period, when complementary foods are given together with either human milk or a breast milk substitute”. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.1423

- The United States Infant Formula Act (1980) does not limit its definition of infant formula to a formula that satisfies all the nutritional needs of an infant. It defines infant formula as “… a
### 2 DESCRIPTION

#### 2.1 Product Definition

2.1.1 [Name of product] for young children means a product manufactured for use as a breast-milk substitute, as a liquid part of the diversified diet of young children and is not necessary to meet the nutritional needs of young children.

2.1.2 Name of product for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all recommended conditions of handling, storage, use and distribution in the country where the product is sold.

#### 2.2 Other Definitions

2.2.1 The term young child means a person from the age of more than 12 months up to the age of three years (36 months).

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**IBFAN**

- ISDI supports this Recommendation even though it remains of the opinion that the word “specially” should be retained.
- ISDI welcomes the deletion of “as a breast milk substitute” in the sentence.
- With respect to the word “specially”, ISDI takes note of the discussions at CCNFSDU39.
- Young children have particular nutritional requirements and this product contributes to these.
- The [Name of product] for young children remains a “food for special dietary uses” in line with the GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 146-1985) that describes “Foods for Special Dietary Uses (FSDU) are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.”
- ISDI would like to highlight the eWG that the last revised Standard for infant formula and formula for special medical purposes intended for infants (Codex STAN 72-1981, rev.2007) and the Guidelines on formulated complementary foods for older infants and young children (CAC/GL 8-1991, rev. 2013) stipulate...
these products are “specially manufactured” and “specifically formulated” respectively. Both are Foods for Special Dietary Uses and the terminology “specially manufactured”/“specifically formulated” refers to the nutritional requirements provided by these products.

• With regard to the reference ‘substitute for breast milk’, ISDI finds it appropriate the product in the Standard is not defined as a ‘breast milk substitute’.

ISDI reiterates that the revised standard for Follow-up formula lays down compositional requirements for [Name of product] for young children. It is critical to point out that its composition is not the same as Infant formula or breast milk and it does not constitute the sole source of nutrition. For example, the revised standard for [Name of product] for young children lays down mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc). In comparison, the current Infant Formula Standard lays down mandatory requirements for 28 micronutrients. There are also differences between both products in terms of the mandatory requirements for macronutrients. Therefore, it would be factually incorrect to define [name of product] for young children as a ‘breast milk substitute’. In fact, such terminology:
• would introduce risk as it could lead parents/caregivers to believe that these products are a suitable replacement for breast-milk. This could result in serious adverse health consequences if these products were mistakenly used as a sole source of nutrition (e.g. 0-6 months).
• would contravene the general principles of labelling ‘Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect’ (Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods).
• would contravene the purpose of the WHO Code on Marketing of Breast-milk Substitutes.

2.1.1 [Name of product] for young children means a product specially [formulated and] manufactured for use as a breast milk substitute [as a breast milk substitute], as a liquid part of the [progressively] [diversified] diet of young children [in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements].

UNICEF
The World Health Assembly has called on Governments to implement the recommendations contained in the 2016 WHO Guidance on ending the inappropriate promotion of foods for infants and young children. Recommendation 2 of that Guidance states that: “A breast-milk substitute 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). 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. The text must thus retain reference to the fact that these products are breastmilk substitutes and should read: '[Name of product] for young children means a product manufactured for use as a breast-milk substitute, as a liquid part of the diversified diet of young children.

2.1.2 Agreed with deletion of the strikethrough text in square brackets

Recommendation 11

9. **LABELLING**

The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

<table>
<thead>
<tr>
<th>Country</th>
<th>Notes and Reactions</th>
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</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australia notes the Codex Procedural manual states text from other Codex documents should not be reported, instead a reference to the relevant documents should be included. As the text in square brackets is already covered in the Guidelines for Use of Nutrition and Health Claims we can SUPPORT deletion of the text.</td>
</tr>
</tbody>
</table>
| Brazil        | Brazil would like to request clarification about Recommendation 11, especially about the decision to delete the statement 'These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation'. In this regard, we consider that the text contained within the square brackets (in bold) should be retained. However, if the Committee agrees to delete the sentence, we consider that it is necessary to include a new specific item in the labelling requirements which clearly states that nutrition and health claims shall not be permitted for FUF. In our opinion, this approach is important to reaffirm the statement presented in the CXG 23-1997 clarifying that the Committee considered that the use of nutrition and health claims are not appropriate for FUF. Moreover, we note that the argument presented to justify the deletion of the sentence related to CXG 2-1985 is not consistent with the approach adopted for others labelling requirements presented in the proposed standard, such as ‘date marking and
The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

<table>
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<tr>
<th>Country</th>
<th>Text</th>
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<tbody>
<tr>
<td>Canada</td>
<td>Since these same prohibitions against nutrient and health claims are present in the infant formula standard, it is necessary to reiterate, for consistency and clarification, that such nutrition and health claims are also inappropriate in FUF for young children. Canada disagrees with the recommendation to agree to the revised text and supports retaining the last sentence. Since these same prohibitions against nutrient and health claims are present in the infant formula standard, it is necessary to reiterate, for consistency and clarification, that such nutrition and health claims are also inappropriate in FUF intended for older infants.</td>
</tr>
<tr>
<td>Colombia</td>
<td>Colombia considers that text in brackets can be deleted considering that conditions for using nutritional and health claims are explicit in CAC/GL 23-1997 (number 1.4). We recommend reviewing the nomenclature (CXG 23 or CAC/GL 23). Colombia proposes new wording (add bold text). Colombia wants that Health and Nutritional Claims always be supported with scientific evidence.</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>Costa Rica supports this recommendation. The crossed-out text is included in the Codex Guidelines for Use of Nutrition and Health Claims (CAC-GL 23-1997). This recommendation refers to this document and, therefore, this text does not need to be repeated.</td>
</tr>
<tr>
<td>Cote d’Ivoire</td>
<td>Cote d’Ivoire supports the text as proposed. 9.1.1, 9.1.2, 9.1.3 a) b) c), 9.1.4: Cote d’Ivoire supports the proposals.</td>
</tr>
<tr>
<td>EU</td>
<td>The EU agrees with the Chairs’ recommendation. As noted previously, the text in square brackets is already covered by the referenced Guidelines for Use of Nutrition and Health Claims and it is therefore redundant.</td>
</tr>
<tr>
<td>Ghana</td>
<td>The Codex Standard and Guidelines mentioned in the text are exhaustive to cover the labelling requirements of this product.</td>
</tr>
<tr>
<td>India</td>
<td>Storage instructions’. In this case, we highlight that the Recommendation 15 repeats texts already presented in the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985).</td>
</tr>
<tr>
<td><strong>Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.</strong></td>
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<tr>
<td><strong>The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.</strong></td>
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<td><strong>The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.</strong></td>
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</tbody>
</table>

The strikethrough out text should be retained to provide emphasis on the prohibition on the use of nutrition and health claims for foods for infants and young children.

**Indonesia**
In line with the previous section, Indonesia does not support the deletion of the last sentence. Indonesia proposes the following changes to the last sentence of the introductory paragraph:

**New Zealand**
Recommendation 11: New Zealand supports the proposed introductory paragraph to the Labelling Section for [name of product] for young children and the deletion of the text.

**Norway**
We continue to support the text that explains that the requirements in the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) include a prohibition on the use of nutrition and health claims. We consider it important to highlight the prohibition on the use of nutrition and health claims for foods for infants and young children. Furthermore, this is consistent with the Infant Formula Standard. We recognise there is no procedural impediment to duplicate what is already covered by the Nutrition and Health Claims guidelines. Furthermore, in this case we consider it particularly relevant and essential to reiterate the prohibition in this standard.

**Philippines**
We propose to retain the statement “These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children as provided and in compliance with the Codex Guidelines on Health and Nutrition Claims for Food Use. While this is already covered by the Nutrition and Health Guidelines, it is still necessary to emphasize that all types of health and nutrition claims should not be allowed on labels of follow up formula for older infants. We believe that the proposed statements are sufficient to prevent any claims on follow up formula. To date, no health and nutrition claims are allowed on any Codex Standards for foods for infants and young children.
The requirements of the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

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<tr>
<th>Country</th>
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<tr>
<td>Senegal</td>
<td>Recommendation 11</td>
<td>Senegal approves the text as proposed with the strikethrough text.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Support to keep the sentence &quot;These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.&quot;</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>The United States supports Recommendation 11 for the introductory paragraph to the Labelling Section for [Name of product] for young children.</td>
<td></td>
</tr>
<tr>
<td>HKI</td>
<td>HKI supports the text as proposed.</td>
<td></td>
</tr>
<tr>
<td>IBFAN</td>
<td>ISDI supports the proposed text for the introductory paragraph to the Labelling section, including a reference to the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). ISDI notes that the text in ‘strikethrough’ is addressed in the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). These guidelines are referenced in this recommendation and therefore this text should not be repeated. ISDI supports that nutrition and health claims are permitted for [name of product] for young children and proposes the following paragraph:</td>
<td></td>
</tr>
</tbody>
</table>
The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to [name of product] for young children. Nutrition and Health claims may be permitted provided, in the case of health claims, that they have been demonstrated in rigorous studies with adequate scientific standards.

- The valid role of health and nutrition claims has been recognized by national legislation in a number of countries.
- Certain health and nutrition claims on labels for foods intended for healthy young children are already allowed in a number of countries.
- Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) already lays down detailed instructions to ensure that the claims made for the foods are substantiated.
- The Global Strategy for Infant and Young Child Feeding states, “Mothers ... should be supported to optimize their infants’ nutrition.” Nutrition and health claims on [Name of Product] for Young Children are a sensible way to encourage optimized nutrition for young children who are not breast-fed.
- Young children need nutrient dense foods to meet their unique nutrient and energy requirements. Most adult food is not able to provide such density.
- Furthermore, young children consume a diverse diet of foods, many of which can bear nutrition and health claims, and [name of product] for young children should be similarly allowed to include nutrition and health claims.
- It is crucial that parents and caregivers are able to make appropriate and informed choices about feeding their young children. Parents and caregivers need access to science- and evidence-based information and statements about the role of nutrients in the growth and development of their young children to support their nutrition decisions.
- When making a food choice, parents and caregivers often compare the label of foods used by general population with products which are classified by Codex as Foods for Special Dietary Uses. Foods used by general population are not specially formulated for young children and are not subject to additional safety criteria. However, the label of foods used by general population often carry nutrition and health claims and these claims could lead parents and caregivers to believe that these foods are superior. This could potentially lead to unhealthy food choices for young children and create unequal conditions for competition.
The requirements of the *Codex* General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

**UNICEF**

Agreed with the reinsertion of the strikethrough text for the same reasoning as stated in relation to the equivalent provision applied to follow-up formula for older infants above. The strikethrough text should be maintained. The World Health Assembly first expressed its concern in 2005 that “nutrition and health claims may be used to promote breast-milk substitutes as superior to breastfeeding”, calling on Governments to “ensure that nutrition and health claims are not permitted for breast-milk substitutes, except where specifically provided for in national legislation”. This was reiterated in 2010 when the Assembly called on Governments to “ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation. Despite these warnings, manufacturers of breastmilk substitutes continue to make such claims on labels of their products around the world, as demonstrated in IBFAN’s Breaking the Rules, Stretching the Rules 2017 global Code monitoring report:

“Unfounded health claims. Claims have become a prime marketing tool. Adding complicated ingredients to formula gives rise to ever more health claims protecting the baby from everything and anything. Many of these additives are then used as trademarked logos, mascots or benefit icons, to protect the company’s exclusive usage. More importantly, such logos and icons serve to push ‘fortified’ or ‘premiumised’ formulas without having to use brand names, circumventing the Code.”

Given the emphasis the World Health Assembly has placed on the need to prohibit health and nutrition claims in respect of the products subject to the standard under consideration, and the continued, well-document use of such claims by the manufacturers of these products, it is in the best interest of infants and young children that the prohibition be stated clearly in the standard.

**Recommendation 12**

9.1 **The Name of the Product**
9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).
9.1.2 The name of the product shall be [Name of Product] for Young Children as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

[84]9.1.3 The sources of protein in the product shall be clearly shown on the label.

a) If [name of animal] milk is the only source of protein*, the product may be labelled ‘[Name of Product] for Young Children Based on [name of animal] milk [protein].

b) If [name of plant] is the only source of protein*, the product may be labelled ‘[Name of Product] for Young Children Based on [name of plant] [protein].

c) If [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled ‘[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein’ or ‘[Name of Product] for Young Children Based on [name of plant] protein and [name of animal] milk protein’.
**9.1.3** The sources of protein in the product shall be clearly shown on the label.

   a) If [name of animal] milk is the only source of protein\[\*\], the product may be labelled ‘[Name of Product] for Young Children Based on [name of animal] milk protein’.

   b) If [name of plant] is the only source of protein\[\*\], the product may be labelled ‘[Name of Product] for Young Children Based on [name of plant] protein’.

   c) If [name of animal] milk and [name of plant] are the sources of proteins\[\*\], the product may be labelled ‘[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein’ or ‘[Name of Product] for Young Children Based on [name of plant] protein and [name of animal] milk protein’, with the main source being mentioned first.

\[\*\] For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

---

**Australia**

9.1.2 Australia supports the proposed text in square brackets.

9.1.3 Australia does not consider 9.1.3 a), b), c) are required for [name of product] for young children.

We propose a simpler approach which is consistent with the Codex Infant Formula Standard. This would retain the first line which requires the protein source to be declared and allows for appropriate identification. We also note that CODEX STAN 1-1985 General Standard for the Labelling of Prepackaged Food specifies the foods and ingredients known to cause hypersensitivity should be declared.

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**Brazil**

Brazil has no opposition to Recommendation 12. However, we note that if our comments related to the name of product is accepted by the Committee (see comments on Recommendation 19) it will be necessary to revise the requirements set in section 9.1.3.

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**Canada**

Canada agrees with the recommendations.

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**Colombia**

Colombia supports proposed text.

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**EU**

The EU agrees with the Chairs’ recommendation which ensures consistency with the similar text agreed for follow-up formula for older infants.

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**India**

Indonesia supports the proposed text in section 9.1.3

Indonesia supports the proposed text in section 9.1.4

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**New Zealand**

NZ comment on recommendation 12:

New Zealand supports and agrees to the draft text as presented.
[*For the sake of clarity, it should be specified that the addition of different amino acids, if necessary to improve protein quality, does not exclude the use of the above labelling options.]

**9.1.46** A product which contains neither milk nor any milk derivative [shall] [may] be labelled "contains no milk or milk products" or an equivalent phrase.

**Mali**
Mali accepts the text as proposed.

**Norway**
We support the proposal.

**Philippines**
The Philippines is supportive of the Statements 9.1.1-9.1.4. The use of "shall" is preferred in Statement 9.1.4 since it is more reinforcing than "may".

**Senegal**
Recommendation 12
Position: 9.1.1, 9.1.2, 9.1.3 a) b) c), 9.1.4: Senegal supports the proposals.

**Switzerland**
Switzerland supports recommendation 12.

**USA**
The United States supports Recommendation 12 the following text for The Name of Product Section 9.1 for [Name of product] for Young Children but with the deletion of "or regional."

**HKI**
9.1.2 HKI supports the text as proposed.
9.1.3 a), b), c) and * HKI supports the text as proposed.
9.1.4 HKI supports the text as proposed.

**IBFAN**

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**9.1** The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be Name of Product for Young Children as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

a) If [name name of animal] animal milk is the only source of protein*, the product may be labelled 'Name of Product for Young Children Based on [name name of animal] animal milk protein'.

b) If [name name of plant] plant is the only source of protein*, the product may be labelled 'Name of Product for Young Children Based on [name name of plant] plant protein'.

c) If [name name of animal] animal milk and [name name of plant] plant are the sources of proteins*, the product may be labelled 'Name of Product for Young Children Based on [name name of animal] animal milk protein and [name name of plant] plant protein' or 'Name of Product for Young Children Based on [name name of plant] plant protein and [name name of animal] animal milk protein'.

[* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]
for Young Children Based on name of plant protein and name of animal milk protein. For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.
9.1.45 A product which contains neither milk nor any milk derivative shall be labelled “contains no milk or milk products” or an equivalent phrase.

<table>
<thead>
<tr>
<th>ISDI</th>
<th>ISDI supports this recommendation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNICEF</td>
<td>9.1.2, 9.1.3 a), b), c) Agreed with deletion of the square brackets. 9.1.4 Agreed with deletion of the square brackets and strikethrough text.</td>
</tr>
</tbody>
</table>

**Recommendation 13**

**9.2 List of Ingredients**

**9.2.1** A complete list of ingredients [including optional ingredients] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes names for these ingredients and additives may be included on the label. [The food additives INS number may also be optionally declared.]

<table>
<thead>
<tr>
<th>Argentina</th>
<th>Recommendation 13: Argentina agrees with the proposed text in 9.2.1. With respect to section 9.2.2, Argentina suggests the following wording: “The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for these additives shall be included on the label. The food additive INS number may also be optionally declared.” It should be noted that, unlike additives, ingredients do not have standardized functional classes. In addition, Argentina believes that each additive must include its functional class.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australia can support the Chair’s proposed changes in the interest of progressing this work, however we note that the proposed text replicates general labelling specifications.</td>
</tr>
<tr>
<td>Brazil</td>
<td>Brazil supports Recommendation 13.</td>
</tr>
<tr>
<td>Canada</td>
<td>Canada agrees with the recommendation for 9.2.1 and 9.2.2</td>
</tr>
<tr>
<td>Colombia</td>
<td>Colombia supports proposed text.</td>
</tr>
<tr>
<td>Cote d’Ivoire</td>
<td>9.2.1, 9.2.2: Cote d’Ivoire supports the text proposals as...</td>
</tr>
</tbody>
</table>
9.2.1 A complete list of ingredients including optional ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes names for these ingredients and additives may be included on the label. [The food additives INS number may also be optionally declared the INS number.]

<table>
<thead>
<tr>
<th>Country</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EU</strong></td>
<td>With respect to section 9.2.1, the EU agrees with the Chairs’ recommendation which ensures consistency with the similar text agreed for follow-up formula for older infants. With respect to section 9.2.2, the EU can agree with the Chairs’ proposal to slightly rephrase the provision in line with that found in the Infant Formula Standard provided that provision 9.2.2 for follow-up formula for older infants is also changed accordingly, in order to ensure consistency.</td>
</tr>
<tr>
<td><strong>India</strong></td>
<td>The strikethrough text [including optional ingredients] should be retained. The strikethrough text [functional] should be retained.</td>
</tr>
<tr>
<td><strong>Indonesia</strong></td>
<td>Indonesia supports the proposed text in Section 9.2 and proposes to open square brackets.</td>
</tr>
<tr>
<td><strong>Malaysia</strong></td>
<td>Malaysia does not agree the recommendation in paragraph 9.2.2 which specific name for food additive should be declared as it is not in line with the paragraph 4.2.3.3 in General Standard for the Labelling of Prepackaged Foods (CXS 1-1985). The standard CXS 1-1985 requires the functional classes shall be used together with the specific name or recognized numerical identification such as the Class Name and the International Numbering System for Food Additive (CXG 36-1989) as required by national legislation.</td>
</tr>
<tr>
<td><strong>New Zealand</strong></td>
<td>Recommendation 13: New Zealand notes that within the Infant Formula Standard, and the proposal for Follow-up Formula for Older Infants, the declaration of the INS number is optional (as also drafted within provision 9.2.2 above). This differs to the requirement within the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), whereby the declaration of the INS number is mandatory. New Zealand is interested to know if there was a conscious decision by the Committee to not require the declaration of the INS number when the Infant Formula Standard was last reviewed. If so, this decision should follow through for Follow-up Formula for Older Infants and for [Name of Product] for Young</td>
</tr>
</tbody>
</table>
Children.
New Zealand supports the deletion of 'functional' within provision 9.2.2. This terminology is used in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) where 'functional' is specific to additives only. As provision 9.2.2 extends to ingredients as well as additives the use of the term 'functional' is not appropriate in this context. We acknowledge that in order to maintain consistency, this may result in the need to also realign provision 9.2.2 for follow-up formula for older infants, which was discussed and agreed to at CCNFSDU39.

**Norway**
We agree with the proposal, and suggest deleting “including optional ingredients”.

**Philippines**
We support deletion of the bracketed phrase "including optional ingredients" in Statement 9.2.1 and ‘the INS number in Statement 9.2.2.

**Senegal**
Recommendation 13
Position:
9.2.1, 9.2.2: Senegal supports the text proposals as presented.

**Switzerland**
Switzerland supports recommendation 13.

**HKI**
9.2.1
HKI supports the text as proposed.

**IBFAN**
International Special Dietary Food Industries
ISDI supports this recommendation. However section 9.2.2. addresses how some ingredients ought to be labelled. ISDI believes the labelling of these ingredients is captured in the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985) and therefore does not need to be repeated.

**UNICEF**
9.2.1
Agreed with deletion of the square brackets.

### 9.2 List of Ingredients

**9.2.1** A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

**9.2.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate classes names for these ingredients and additives may be included on the label. (The food additives INS number may also be optionally declared - the INS number.)
Recommendation 14

9.3 Declaration of Nutritive Value

The declaration of nutrition information for [name of product] for young children shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold [as well as] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

Argentina
Recommendation 14: Argentina agrees with the proposed text in sections 9.3.a) and 9.3.b).

It should be noted that the Argentine Food Code does not define servings for infants and young children up to 36 months.

Australia
Australia supports the proposed changes.
For c) Australia considers the inclusion of the text in square brackets ‘per serving size and/or’ is appropriate as these products are consumed as servings.

Brazil
Brazil supports recommendation 14 with the following amendments:

  c) In addition, the declaration of nutrients in a) and b) per serving size, in countries where serving sizes are normally used, and/or per 100 kilocalories (or per 100 kilojoules) is permitted.

In this sense, we note that: a) in some countries serving sizes are normally used, including for foods intended for children under 36 months; b) the declaration of nutrients per serving size is optional and c) the Guidelines on Nutrition Labelling (CAC/GL 2-1985) states that “in countries where serving sizes are normally used, the information required by Sections 3.4.2, 3.4.3 and 3.4.4 may be given per serving only as quantified on the label or per portion provided that the number of portions contained in the package is stated, including for foods intended for children under 36 months”.

Canada
Canada agrees with the recommendation 9.3 a), b), c)

Colombia
Colombia supports proposed text.

Cote d’Ivoire
<table>
<thead>
<tr>
<th>Position:</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.3 a) b) c): Côte d’Ivoire approves the text as proposed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ecuador</th>
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<tbody>
<tr>
<td>9.3 Ecuador believes it is important not to use the term “food sold”, but rather the term “reconstituted food” or “food ready for consumption”.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>EU</th>
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<tbody>
<tr>
<td>The EU agrees with the Chairs’ proposal to include the text “as well as” and delete “or” in section 9.3. As noted in the contribution to the eWG, leaving the choice between the two alternatives to operators could create confusion when comparing products. With respect to provision c) The EU does not support the proposal to add the words “per serving size”, as this would in any case be allowed under certain conditions established in the Guidelines on Nutrition labelling (CAC/GL 2-1985), which apply anyway to (name of the product) for young children. The Follow-Up Formula Standard should only include requirements that are different from, or better specify, general principles included in horizontal CODEX texts that apply anyway to the product.</td>
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<table>
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<tr>
<th>India</th>
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<tbody>
<tr>
<td>9.3 a), b) India suggests that bracketed text [as well as] should be included.</td>
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</table>

<table>
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<tr>
<th>Indonesia</th>
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<tbody>
<tr>
<td>Indonesia supports the proposed text in section 9.3 and proposes to open square brackets.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Malaysia</th>
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</thead>
<tbody>
<tr>
<td>Malaysia would like to propose that for [Name of product] for young children, the nutrients shall be declared in per serving size for better information and understand to the consumer. This approach is in line with Malaysia Food Regulations 1985.</td>
</tr>
</tbody>
</table>

**The declaration of nutrition information for [name of product] Follow-up Formula for young children shall contain the following information which should be in the following order:**

* c) In addition, the declaration of nutrients in a) and b) per [serving size and/or per] shall be given – 100 kilocalories (or per 100 kilojoules) is permitted.

**Clean copy**

9.5 Information for use

9.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

9.5.5 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a diversified diet.

**Recommendation 14**

New Zealand supports and agrees to the draft text as presented, including the addition of ‘serving size’ in c).

NZ comment on recommendation 15:

New Zealand supports and agrees to the draft text as presented.

NZ comment on recommendation 16:

New Zealand supports the modified 9.5.1 to align with that for follow-up formula for older infants. We also support 9.5.2 including the proposed amendments.

We also agree with the deletion of the text within provision 9.5.3 as this is best included and covered within Section 9.6 of the Standard. New Zealand is also of the view that instructions illustrating the method of preparation are important, but for [name
9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a diversified diet. The label of [name of product] for young children these need not be graphic. We have therefore included a modification to 9.5.3. We suggest that provision 9.5.4 should be deleted as a warning on ‘health hazards’ is not appropriate for this product which is not considered to be nutritionally necessary in the diets of young children, and which would be consumed in addition to other general purpose foods. Furthermore, we consider that key issues regarding safety are covered within provision 9.5.2 and do not need to be repeated.

We support the draft text within provision 9.5.6 as presented.

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**Norway**

9.3c) We agree with the proposed text, except for not being in favour of permitting declaration of nutrients per serving size, as serving size is an undefined measure.

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**Senegal**

Recommendation 14: Position: 9.3 a) b) c): Senegal approves the text as proposed.

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**Switzerland**

Switzerland supports recommendation 14.

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**USA**

In addition, the declaration of nutrients in a) and b) per [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

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**HKI**

9.3a), b), c) HKI supports the text as proposed.

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**IBFAN**

9.3 Declaration of Nutritive Value The declaration of nutrition information for [name of product] for young children shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold as well as [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold as well as [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

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**ISDI**

ISDI supports this recommendation.

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**UNICEF**

9.3 Agreed with deletion of square brackets and strikethrough text. 9.3 a) b) c) Agreed with deletion of square brackets and strikethrough text.
## Recommendation 15

### 9.4 Date Marking and Storage Instructions

**9.4.1 (i)** The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, at least the month and year shall be declared. The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM.).

(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words “Best before end <insert date>; or “Best Quality Before end <insert date>.

### 9.4.2

In addition to the date, any special conditions for the storage of the food shall be indicated if where they are required to support the integrity of the food and, where the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.

<table>
<thead>
<tr>
<th>Country</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>supports the proposed text as consistent with the majority of views of the eWG</td>
</tr>
<tr>
<td>Brazil</td>
<td>requests clarification about the use of “Best Before Date” or “Best Quality Before Date” instead of “Use–by Date” or “Expiration Date”. The CXS 1-1985 states that when a food must be consumed before a certain date to ensure its safety and quality “Use–by Date” or “Expiration Date” should be used. In this regard, we consider that a follow-up formula should not be consumed after the expiration date, since there is no guarantee of the compliance with the standardized nutritional, microbiological and other quality and safety requirements. Moreover, it is necessary to consider that this product is intended for use for children under 36 months which are a very special and vulnerable population.</td>
</tr>
<tr>
<td>Canada</td>
<td>agrees with the recommendation 9.4, 9.4.1 (i), 9.4.2</td>
</tr>
<tr>
<td>Colombia</td>
<td>supports proposed text</td>
</tr>
<tr>
<td>The EU</td>
<td>agrees with the recommendation which ensures consistency with the same provisions agreed for Follow-Up Formula for older infants in CCNFSDU39.</td>
</tr>
<tr>
<td>Ghana</td>
<td>Section 9.4.1 (i) Codex Stan 1 as mentioned in the labelling section gives comprehensive requirements for date marking in Section 4.7.1 (ii - viii). We therefore see this section as a repetition. This subsection is provided for in the Codex Stan 1n subsection 4.7.2. It is a repetition as the Standard has been stated in the labelling requirements of this Standard.</td>
</tr>
<tr>
<td>Indonesia</td>
<td>supports the proposed text in section 9.4</td>
</tr>
<tr>
<td>Norway</td>
<td>support the proposed text.</td>
</tr>
<tr>
<td>Philippines</td>
<td>support deletion of the brackets in Statement 9.4.1.</td>
</tr>
<tr>
<td>Senegal</td>
<td>9.4.1 i) and 9.4.2: Senegal supports the proposals.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>supports recommendation 15.</td>
</tr>
<tr>
<td>The United States</td>
<td>supports Recommendation 15 for Date Marking and Storage Instructions for [name of product] for young children and removal of the square brackets.</td>
</tr>
<tr>
<td>USA</td>
<td>9.4, 9.4.1 (i), 9.4.2 HKI supports the text as proposed and believes that this text and the equivalent text relating to follow-up formula for older infants should be aligned.</td>
</tr>
<tr>
<td>HKI</td>
<td>9.4 Date Marking and Storage Instructions (i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, at least the month and year shall be declared.</td>
</tr>
<tr>
<td>IBFAN</td>
<td>supports the proposed text.</td>
</tr>
</tbody>
</table>
The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).

(ii) In the case of products requiring a declaration of month and year only, the [date shall be introduced by the words "Best before end insert date; or "Best Quality Before end insert date. Where practicable, storage instructions shall be in close proximity to the date marking.

Where practicable, storage instructions shall be in close proximity to the date marking.

ISDI supports this recommendation.

**Recommendation 16**

<table>
<thead>
<tr>
<th>Section</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5 1</td>
<td>[Ready to use] products in liquid form <em>should</em> may be used [either] directly, or in the case of concentrated liquid products [and powdered products], must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.</td>
</tr>
<tr>
<td>9.5 2</td>
<td>Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula [product] remaining after feeding should be discarded, shall appear on the label.</td>
</tr>
<tr>
<td>9.5 3</td>
<td>The label shall carry clear graphic instructions illustrating the method of preparation of the product. [Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]</td>
</tr>
<tr>
<td>9.5 4</td>
<td>The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.</td>
</tr>
<tr>
<td>9.5 5</td>
<td>Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.</td>
</tr>
<tr>
<td>9.5 6</td>
<td>The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] [balanced] diet.</td>
</tr>
</tbody>
</table>

Argentina agrees with the proposed text. However, section 9.5.4 should be amended in order to read as follows: "The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use."

**Argentina**

Australia re-iterates support for the approach that labelling should not be more stringent than that for infant formula or follow-up formula for older infants. On that basis Australia supports the Chair’s recommendation to support the text as proposed for 9.5.1, 9.5.2, 9.5.4, and 9.5.5. For 9.5.3, Australia does not support the inclusion of the bracketed text because it is duplicative with the text proposed under 9.6.1 (as agreed as the better location by the 2017 eWG). For 9.5.6, Australia prefers the term 'diversified' because the term 'balanced' implies these products are intended for general use.

Consistent with the appropriate use of [Name of product] for
young children we also suggest adding the additional text ‘and is not suitable as a sole source of nutrition’. Our rationale for adding the text “is not suitable as a sole source of nutrition” is to highlight the different role of these products. This is important to ensure the safe and appropriate use of these products, which provide only a limited number of mandatory nutrients compared to follow-up formula for older infants.

We note an editorial correction is required in 9.5.4, the word ‘and’ after warning needs to be removed.

---

**Brazil supports Recommendation 16.**

9.5.4. [The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use].

9.5.5. Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. Use of graphics is permitted and encouraged for multi-step instructions. [Pictures of feeding bottles are not permitted on labels of [name of product] for young children.]

9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified balanced diet]. “and is not suitable as a sole source of nutrition”.

---

**Canada**

Canada generally agrees with the recommendation. However, Canada prefers the deletion of 9.5.4 and 9.5.5 as these are repetitive and already covered under 9.5.1 and 9.5.2.

---

**Colombia supports proposed text.**

9.5.1 to 9.5.6: Colombia wants to clarify to consumer information.

---

**Cote d'Ivoire**

9.5.1 to 9.5.6: Cote d'Ivoire supports the proposals as presented.

---

**EU**

The EU agrees with the proposed text for Section 9.5 which ensures consistency with the same provision proposed for Follow-Up Formula for older infants.

As noted in the contribution to the eWG, the EU is of the opinion that “information for use” provisions should not be...
more stringent for [Name of Product] for young children than what is proposed for Follow-Up Formula for older infants, or infant formula, taking into account that young children have increasingly diversified diets and that the Codex General Standard for the labelling of prepackaged foods (STAN 1-1985) applies anyway to [Name of Product] for young children.

9.5.3
We propose that, the text reads:
The label shall carry clear instructions illustrating the method of preparation of the product. Use of graphic is encouraged for multi-step preparation.
This is to give flexibility to small packages that can not accommodate the use of graphics.
9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age. It should be used as part of a progressively diversified diet and is not suitable as sole source of nutrition. It should be used as part of a diversified and balanced diet.

Philippines
We are in agreement to delete the brackets in the statements 9.5.1-9.5.5.

Senegal
9.5.4 Senegal supports the proposals as presented.

Switzerland
Overall, Switzerland generally supports the proposal related to provision 9.5.4
9.5.4 Switzerland seeks the removal of the redundant “and” in 9.5.4.
9.5.6 For Switzerland, a diet shall be diversified and balanced at the same time.

USA
The United States supports Recommendation 16 for the following text for Information for Use for [name of product] for young children with the removal of the square brackets and deletions

IBFAN
9.5 Information for use
9.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powdered form must contain a statement that the product is not sterile and preparation instructions must include that the product be reconstituted with safe water at 70 degrees centigrade. (WHO/FAO (2007) guidelines “the Safe preparation, storage and handling of powdered infant formula (http://apps.who.int/iris/bitstream/handle/10665/43659/9789241595414_eng.pdf?sequence=1) and WHA resolutions WHA 58.32 (2005) and 61.20 (2008) as well as the Codex Alimentarius ‘Code of hygienic practice for powdered formulae for infants and young children’ (2008) which provides relevant recommendations for the labeling of powdered infant formula and follow-up formula. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.
9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.
9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.
9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a diversified diet. The label of name of product for young children shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of name of product for young children. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label. Remove brackets.

ISDI
<table>
<thead>
<tr>
<th>Section</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5.3</td>
<td>ISDI generally supports this recommendation.</td>
</tr>
<tr>
<td>9.5.3</td>
<td>ISDI suggests to slightly modify 9.5.3, to read “The label shall carry clear instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions”.</td>
</tr>
<tr>
<td>9.5.4</td>
<td>ISDI suggests to Remove “and “ in 9.5.4.</td>
</tr>
<tr>
<td>9.5.6</td>
<td>ISDI recommends that the section 9.5.6. is cross-referenced in section 9.6. [Additional labelling requirements] and reads as follows.</td>
</tr>
<tr>
<td></td>
<td>This additional wording: “and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition”.also ensures that:</td>
</tr>
<tr>
<td></td>
<td>□ Parents/caregivers are provided with clear and accurate information on feeding</td>
</tr>
<tr>
<td></td>
<td>□ There is no contravention to the general principles of labelling “Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect’ (Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods)</td>
</tr>
<tr>
<td>9.5.1</td>
<td>HKI recommends that the word ‘potable’ be deleted but can accept the text with it included. Otherwise HKI supports the text as proposed.</td>
</tr>
<tr>
<td>9.5.2</td>
<td>HKI supports the text as proposed - deletion of square brackets, deletion of strikethrough text. HKI points out a grammatical error – there should be no ‘s’ on the end of the word preparations.</td>
</tr>
<tr>
<td>9.5.3</td>
<td>HKI understands the justification given by the Chair of the EWG that there is already a prohibition on the use of images of bottles on the labels of these products, however we believe this should be reinforced in this text. HKI proposes that the text read “The label shall carry clear graphic instructions illustrating the method of preparation of the product, but such graphics shall not include pictures of feeding bottles.”</td>
</tr>
<tr>
<td>9.5.4, 9.5.6</td>
<td>HKI supports the text as proposed.</td>
</tr>
</tbody>
</table>

**Product graphics is permitted and encouraged for multi-step instructions.** [Pictures of feeding bottles are not permitted on labels of (name of product) for young children.] **The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.** **The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified [balanced] diet] and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition.** **[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]**
Recommendation 17

9.6 Additional Labelling Requirements

| 9.6.1 | The label of [name of product] for young children shall have no image, text or representation [including pictures of feeding bottles] that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label. |
| 9.6.2 | Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used. |

For 9.6.1 and 9.6.2 Australia supports inclusion of the text in square brackets. For 9.6.2 Australia supports deletion of considerations at the end of this provision i.e. "[in particular as to the text, images and colours used]". We consider that this text lacks clarity and is open to differing interpretations. Australia

We suggest including the sentence "It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond" in section 9.6.1 in line with recommendation 4 of WHA 69.9.

In relation to the section 9.6.2, we support the text in square brackets as it is accordance with recommendation 5 of WHA 69.

Recommendation 5. There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children.

1) The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).

In this matter, Brazil considers that if the Committee considers that the text could be misinterpreted, it is more reasonable to rewrite the sentence considering the WHA 69.9 references instead of only deleting it. Brazil

9.6, 9.6.1, 9.6.2 Canada agrees with recommendation Canada

Colombia supports proposed text. Colombia

| 9.6.1 | The label of [product name] for young children shall not contain any image, text or representation, including images of bottles, that likely to interfere with or discourage breastfeeding, or that idealises the use of [product name] for young children. The words "humanized", "mothered" or other similar terms should not be used on the label. |
| 9.6.2 | The product shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [product name] for young children and formula for special medical purposes, and to enable consumers to clearly distinguish between them by means of different texts, images and colours. |

Cote d'Ivoire

9.6.1: Cote d'Ivoire approves the text as proposed
9.6.2: Cote d'Ivoire does not approve the text as drafted and suggests the following redraft: "The product shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [product name] for young children and formula for special medical purposes, and to
enabl enable consumers to clearly distinguish between them by means of different texts, images and colours."

<table>
<thead>
<tr>
<th>9.6 The additional labelling requirements for this product should be the same as those for complementary formulas for older infants.</th>
</tr>
</thead>
</table>

**Ecuador**

References
2. WHO. http://www.who.int/nutrition/topics/WHA54.2_iycn_en.pdf-

**India**

Section 9.6 in the existing standards for Follow-up Formula which states "The products covered by this standard are not breast-milk substitutes and shall not be presented as such." needs to be revised in view of the guidance on ending the inappropriate promotion of foods for infants and young children (2016) http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf developed by WHO since this applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 months. The guidance recommends, “Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milks (or products that could be used to replace breast milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for

**EU**

The EU agrees, in general, with the recommendation proposed by the Chair which aims at ensuring that the labelling of Follow-Up Formula for young children does not discourage breastfeeding but at the same time it allows for some level of flexibility at national/regional level. The EU remains of the view that [Name of Product] for young children has a different role in the diet than Follow-Up Formula for older infants which must be taken into account when laying down Standards for the product.

As regards section 9.6.1 the EU welcomes the inclusion of the text “including pictures of feeding bottles”. Such graphics could lead to confusing this product with infant formula or follow-up formula, particular a high risk for illiterate consumers that may rely more on pictures than on text. In addition, in the EU a number of Member States recommend to not feed young children any more with bottles with teats. This ensures that young children are not delayed in the development of typical oral motor skills for this age.

However the EU disagrees with the proposed deletion of the text in square brackets in section 9.6.2. The EU is of the view that it is essential to ensure that products for older infants and products for young children are clearly distinguishable. The best way to achieve this is by including in the Standard a provision clearly specifying how that should be ensured, therefore specific references to the text, images, colours used should be kept in the provision.

The products covered by this standard are breast-milk substitutes and shall be presented as such. Marketing of such products should confirm to provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions.”

[9.6.1] The label of [name of product] Follow-up Formula for young children shall have no image, text or representation [including pictures of feeding bottles,] that could undermine or discourage breastfeeding or which idealises the use of [name of product] Follow-up Formula for young children. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label.

[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] Follow-up Formula for young children, and formula for special medical purposes[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used].

[9.6.3] These products are breast milk substitutes and should be represented as such. Marketing of these products needs to be regulated as per the provisions of the International Code of Marketing of Breast milk Substitutes and subsequent relevant WHA resolutions.
feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). 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.”

### 9.6.1

The text in square brackets should be included

**New 9.6.3**

Insert additional section 9.6.3

<table>
<thead>
<tr>
<th>Indonesia supports the proposed text in section 9.6.1 and 9.6.2, proposes to open square brackets</th>
<th>Indonesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Labelling Requirements</td>
<td>Nepal</td>
</tr>
<tr>
<td>As mentioned above, Nepal believes that these products are also breastmilk substitutes, and therefore, additional labelling requirements for these products should NOT be different from the additional labelling requirements of follow-up formula for older infants.</td>
<td></td>
</tr>
<tr>
<td><strong>CLEAN COPY:</strong></td>
<td>New Zealand</td>
</tr>
<tr>
<td>9.6  Additional Labelling Requirements</td>
<td></td>
</tr>
<tr>
<td>9.6.1 The label of [name of product] for young children shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label.</td>
<td></td>
</tr>
<tr>
<td>9.6.2 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them.</td>
<td></td>
</tr>
</tbody>
</table>

| We support deleting the brackets in the 9.6.1. and 9.6.2. statements.                           | Philippines |
| We also recommend to delete the phrase “as to the text, images and colours used” in Statement 9.6.2 since these could be considered as trade barriers. |            |

**9.6.2** The product shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them by means of different texts, images and colours, thanks in particular to the text, images and colours used.

| Senegal                                                                                         | Swiss Lanka |
| 9.6.1: Senegal supports the text as proposed                                                    |            |
| 9.6.2: Senegal does not support the text as drafted and suggests the following redraft: “The product shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, name of product] for young children, and formula for special medical purposes, and to enable consumers to clearly distinguish between them by means of different texts, images and colours.” |            |

| Sri Lanka                                                                                      | Switzerland |
| 9.6.2: suggest to have similar wording as in follow up formula for older infants.                |            |
| Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, name of product] for young children, and formula for special medical purposes, and to enable consumers to clearly distinguish between them by means of different texts, images and colours. |            |
follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes], and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

USA The United States supports further discussion regarding Recommendation 17 for the Additional Labelling requirements for [name of product] for young children with the following comments for consideration. The United States notes that based on the nutritional composition of the product for young children, it is important that [name of product] for young children be clearly identified as not being suitable as a breastmilk substitute. The [name of product] for young children contains a limited number of essential nutrients and its use as drink in the diet of a young child is designed to address nutrients that may be insufficient.

We consider it essential to point out to the consumer that the composition of this product is not the same as Infant formula (sole source of nutrition). The revised standard for [Name of product] for young children has mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc) as compared to the infant formula standard or the proposed follow-up formula for older infants that requires a complete mandatory nutrient composition.

We also find the words humanized or maternalized or other such terms unhelpful for label use to the consumer but the concepts should be considered as inappropriate for marketing purposes and made suggested edits toward that objective. We note that the bracketed phrase [including pictures of feeding bottles,] does not add clarification regarding the product’s use and consider that these texts be deleted. This product is nutritionally appropriate as a drink and not as a formula which is one of the reasons to consider a separate standard for this product for young children. We consider the text in 9.6.2 acceptable until the last phrase in the last sentence: “in particular as to the text, images and colours used” to represent a clear statement of the limitations of the product and propose the deletion of this wording. We are concerned about the subjective nature of text and the potential to different interpretations and would not want to inadvertently create trade barriers. We suggest consideration be given to an additional wording that provides for alternative packaging shapes.
to provide an easy and distinguishable differentiation among the products and graphics for product preparation so that consumers with low literacy could correctly prepare the product.

HKI
HKI strongly believes that this section of the text has not been discussed comprehensively enough to make any decision and that consensus was NOT reached in the EWG. HKI therefore does not support the recommendation of the EWG report. HKI strongly believes that the additional labelling requirements for this product should be the same as those for follow-up formula for older infants and that the concept of alignment, where possible and relevant, was agreed as a general principle by the Committee. HKI therefore recommends that the text, when agreed for the additional labelling requirements for older infants, then be discussed here.

IBFAN

[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

9.6 Additional Labelling Requirements – These should be aligned to those for follow-up formula for older infants
9.6.1 Labels should not discourage breastfeeding,
Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
   a) the words "important notice" or their equivalent;
   b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;
   c) a statement that the product should only be used on advice of an independent health worker as to the need for its use including that the product is not suitable for infants under the age of twelve months and the proper method of use.
   (d) the statement; ‘The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding’.
9.6.2 Remove brackets. The label shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of name of the product for young children.
   or other representation that might:
   9.6.2.1 idealize the used of name of the product for young children;
   9.6.2.2 suggest use for infants under the age of 12 months (including references to milestones and stages);
   9.6.2.3 recommend or promote bottle feeding;
   9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;
   9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities. Delete regional or international.
| 9.6.3 | The terms “humanized”, “maternalized” or other similar terms that compare the product to breastmilk shall not be used. |
| 9.6.4 | Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images, names, slogans, colours and mascots used. |

**ISDI**

ISDI supports this recommendation and refers to recommendation 16 whereby ISDI suggests to reference section 9.5.6 into this section. Therefore, a new section 9.6.3 would read as follows: [The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] diet] “and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition”.

9.6.2 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.

9.6.3 [The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] diet] “and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition”.

ISDI highlights that section 9.6 (Additional Requirements) of the current Codex Standard for Follow-up Formula Standard states “The products covered by this standard are not breast-milk substitutes and shall not be presented as such”. Although this wording is not captured under revised section 9.6, ISDI proposes that its intent is now captured under 9.5.6 to ensure appropriate use (see ISDI response to Recommendation 16).

There was a strong support within the eWG that [name of product] for young children are not breast milk substitutes. [Name of product] for young children contains a limited number of essential nutrients. It can only be used as part of a diversified diet of a young child.

This additional wording is proposed to clarify the role of [name of product] for young children in the diet.

• The revised standard for Follow-up formula lays down compositional requirements for [Name of product] for young children. It is critical to point out that its composition is not the same as Infant formula (sole source of nutrition) OR breast milk. For example, the revised standard for [Name of product] for young children lays down mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc). In comparison, the current infant formula standard lays down mandatory requirements for 28 micronutrients. There are also differences between products in terms of the mandatory requirements for macronutrients.

This additional wording also ensures that:

• Parents/caregivers are provided with clear and accurate information on nutritional value and composition
• No contravention exists with the general principles of labelling
"Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect" (Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods)

**9.6.2 and new 9.6.3**

ISDI agrees with the removal of language covering "texts, images and colours" in 9.6.2 as this is subjective, open to different interpretations and has significant implications for the facilitation of international trade that would not be consistent with the mandate of Codex. Such texts, images and colours are lawfully registered, legitimate trademarked characteristics and are covered by relevant international obligations pertaining to intellectual property rights. In addition, the ability of consumers to recognize trusted, legitimate brands is important for their identification of safe and suitable products and is essential to prevent adulteration and counterfeiting.

ISDI suggests to reference section 9.5.6. into this section. Therefore, a new section 9.6.3 would read as follows: [The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] diet.] "and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition".

| In the interests of consistency, the additional labelling requirements for this product should be the same as those for follow-up formula for older infants. | UNICEF |