## **European Union Comments**

# CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-ninth Session
Hamburg, Germany, 4-8 December 2017

## Agenda item 4

Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987) at Step 3 (CX/NFSDU 17/39/4)

European Union competence European Union vote

This document provides <u>specific</u> comments on each recommendation made by the eWG Chairs in document CX/NFSDU 17/39/4

#### FOLLOW-UP FORMULA FOR OLDER INFANTS

## **Recommendation 1 (protein)**

Nutrient	Current FUF Standard	IF Standard	eWG Chairs' proposal	Delegated Regulation (EU) 2016/127
Protein (g/100 kcal)	3-5,5	1,8-3	1,6-3	1,6-2,5

The EU agrees with the recommendation with respect to the minimum protein content of 1,6 g/100 kcal, which reflects the European Food Safety Authority (EFSA)'s Scientific Opinion. It concluded that the use of follow-up formula with a protein content of at least 1.6 g/100 kcal from intact cow's milk protein or intact goat's milk protein is safe and suitable for infants living in Europe with an intake of complementary foods of a sufficient quality and could be generalised to healthy infants with comparable dietary intakes living in other countries.

With respect to footnote 5 (soy protein isolates): the EU agrees with the recommendation to add a reference to non-goats milk protein, given that EFSA reviewed only the safety and suitability of follow-on formula, based on cows' milk intact protein or goats' milk intact protein, with a protein content of 1.6 g/100 kcal and provided a favourable opinion. The EU agrees with the recommendation to retain the current protein minimum of 2.25g/ 100kcal for soy protein isolates which is in line with EFSA's advice and is consistent with the Infant Formula Standard.

With respect to footnote 6 (clinical evaluation): the EU agrees with the recommendation to introduce a requirement for clinical evaluation of formula with non-hydrolysed milk protein levels below 1,8 g/100 kcal, given that EFSA's Scientific Opinion cannot be generalised to countries where protein intakes may be lower and/or of poorer quality. Therefore, the EU considers that the evidence remains insufficient to unconditionally warrant the lowering of the protein minimum to 1.6 g/100 kcal. However, for the sake of clarity, the EU suggests to specify in the footnote that one particular formula should be clinically evaluated for its **safety** and **suitability** by a competent national and/or regional authority.

At the same time, as noted in previous occasions, the EU would support introducing a requirement for clinical evaluation for all formulae based on <a href="https://hydrodysed.com/hydrodysed">hydrodysed</a> protein (and not only those containing less than 2,25 g/100 kcal), in line with the requirements in EU legislation (Regulation (EU) 2016/127) and the advice of EFSA. In this context, it should be noted that EFSA published on 11 May 2017 a scientific guidance on the data that food business operators should make available to the Authority when submitting dossiers on formulae manufactured from protein hydrolysates.

In light of the above the following text is proposed for footnote 6:

Follow-up formula based on non-hydrolysed milk protein containing [less than 1.8 g] protein/100 kcal [(0.43 g/100 kJ)] and follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] (0.54 g/100 kJ) should be clinically evaluated for *its safety and suitability* by a competent national and/or regional authority.

## Recommendation 2 (optional addition of DHA)

In previous discussions on the matter the EU had considered it prudent to require the mandatory addition of DHA to Follow-Up Formula for older infants in amounts similar to those in breast milk. This consideration was based on DHA's structural role in the nervous tissue and the retina, its involvement in normal brain and visual development, the need for the developing brain to accumulate large amounts of DHA in the first two years of life and the fact that the intake of pre-formed DHA generally results in a DHA status more closely resembling that of a breastfed infant (than the one achieved with ALA alone). In the spirit of compromise the EU agreed with the principle of voluntary addition, but stressed that, when added on a voluntary basis, DHA should be present at a level that is significant for infants. Taking into account the agreement of CCNFSDU38 to further consider the levels for DHA based on total energy density instead of as a percentage of total fat, the EU would still support a minimum DHA level (in case of voluntary addition) of 20 mg /100 kcal, as recommended by EFSA in its opinion of 2014.

With respect to the GUL the EU agrees with the recommendation to set it at 30 mg/100 kcal to allow for a wider range of DHA levels and to ensure consistency with the Infant Formula Standard.

With respect to the footnote, the EU is of the opinion that different legal interpretations could exist on the footnote and some could argue that it refers only to the DHA/ARA and DHA/EPA ratios. For the sake of clarity, the EU would therefore propose a minor redrafting to the footnote:

If docosahexanoic acid (22:6n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, <u>may set different levels and may require the mandatory addition of docosahexaenoic acid</u>, as appropriate for the nutritional needs.

#### FOLLOW-UP FORMULA FOR YOUNG CHILDREN

#### Recommendation 3 (minimum level for fat of 3.5 g/100 kcal )

The EU agrees with the recommendation of the Chairs to establish a minimum level for fat of 3.5 g/100 kcal in Follow-Up Formula for young children. This level is comparable with that found in reduced fat milk allowing the marketing of Follow-Up Formula based on semi-skimmed milk in those countries that recommend semi-skimmed milk consumption.

## Recommendation 4 (Maximum level for available carbohydrates of 12.5 g/100kcal)

The EU continues to prefer establishing a maximum carbohydrate level of 12g/100kcal, as this level would ensure the nutritional integrity of the product, taking into account the composition of either full fat or semi-skimmed milk and formulas.

#### **Recommendation 5 (Types of carbohydrates)**

The EU welcomes the Chairs' proposal which clarifies the differences in definitions for sugars by replacing "sugars" with "mono-and disaccharides". With respect to the percentage limit for sugars the EU continues to support the setting of a maximum limit for mono-and disaccharides, other than lactose of 10% of available carbohydrates. As noted in the contribution to the eWG, sugar consumption can negatively influence the development of taste preferences of young children, therefore setting a lower limit of 10% of available carbohydrates would be of great importance. The EU acknowledges that there is support in the eWG to bring the limit for free sugar in line with the WHO recommendation. In this context it is worth noting that while WHO recommends limiting the intake of free sugars to less than 10% of total energy intake it also recommends further reduction to less than 5% of total energy intake for additional health benefits.

The EU also agrees with the recommendation to bring the wording in line with the WHO recommendation. In practice, for drinks, the WHO definition of "free sugars" largely covers mono- and disaccharides with the exception of lactose present in dairy products. The EU understood that the proposed reference to mono- and disaccharides encompasses all mono- and disaccharides in [name of the product], irrespective of the way they were incorporated, e.g. as mono- and disaccharides included as such, included as ingredients containing mono- and disaccharides or included during the production process (i.e. enzymatic hydrolysis of starches). The same applies to the reference that sucrose and/or fructose should not be added, unless needed as a carbohydrate source. This encompasses sucrose and/or fructose in [name of the product], irrespective of the way they were incorporated, e.g. as sucrose and/or fructose included as such (i.e. added fructose), included as ingredients containing sucrose and/or fructose (i.e. fruit juice syrups containing high amounts of fructose) or included during the production process (i.e. enzymatic hydrolysis of starches).. The footnote should ensure that all those forms of mono- and disaccharides and sucrose and/or fructose are covered.

With respect to the restrictions on the use of sweet tasting carbohydrates, the EU agrees with the Chairs' proposal. The EU understands that the wording "other carbohydrates contributing to the sweet taste of [name of product]" is comprehensive and includes non-available carbohydrates as those can contribute significantly to the sweet taste of a product. Also, as noted in the contribution to the eWG, products that are formulated as lactose-free products or products with low lactose contents could contain predominantly polysaccharides, with a sweetness level comparable to the sweetness level of glucose and lead to products with a distinctive sweet taste. Having a maximum limit for available carbohydrates to up to 12g and a limit for mono- and disaccharides other than lactose could still lead to products with a distinctive sweet taste which could potentially negatively influence the development of taste preferences of young children. As an alternative, the EU can accept that other carbohydrates, available or not available, contributing to the sweet taste of [name of product] can be included in the second sentence of the footnote to be included in the list of carbohydrates that are limited in quantity, as proposed in the text below.

The EU considers the restriction "solely" in the last sentence of the footnote to be difficult to enforce. It can be argued that substances or ingredients are added for more than solely one purpose, in order to impart sweet taste. Therefore, the EU proposes to delete "solely".

## Text Proposal:

<sup>4)</sup> Lactose should be the preferred carbohydrate in [name of product] based on milk protein. [Mono- and disaccharides], other than lactose, [and/or other carbohydrates contributing to the sweet taste of [name of product]][, that were added as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means,] should not exceed [210%] of available carbohydrate. [Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.] Sucrose and/or fructose [and/or other carbohydrates contributing to the sweet taste of [name of product]] should not be added [as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means] [and/or other carbohydrates contributing to the sweet taste of [name of product]], unless needed as a carbohydrate source. [Other non-carbohydrate ingredients should not be added [solely] with the purpose of imparting a sweet taste.]

#### Clean version:

<sup>4)</sup> Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, and/or other carbohydrates contributing to the sweet taste of [name of product], that were added as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 10% of available carbohydrate. Sucrose and/or fructose should not be added as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting a sweet taste.

## **Recommendation 6 (Conversion of % limits of sugars)**

The EU continues to prefer presenting the limit as a percentage of available carbohydrates, however, the EU can accept the Chairs' proposal to convert percentage limits to an absolute amount based on the energy density, provided the proposed way of calculation ensures a very restrictive approach.

## **Recommendation 7 (calcium-to-phosphorous ratio)**

The EU agrees with the Chairs that there is no need to establish a calcium/phosphorus ratio in follow-up formula for young children, taking into account that phosphorous is not a key nutrient in cows' milk or a nutrient with inadequate intakes in the diet of young children, and that diets of young children are increasingly diversified providing phosphorous from other sources.

## **Recommendation 8 (Vitamin D)**

The EU continues to support the setting of a minimum level of 1  $\mu$ g/100 kcal and a maximum level of 3  $\mu$ g/100 kcal which align with the levels agreed to for Follow-Up Formula for older infants in line with the pragmatic approach followed in the Committee for the mandatory

addition of other micronutrients whose intakes are widely inadequate in the diet of young children.

## SCOPE AND LABELLING-OLDER INFANTS (6-12 MONTHS)

#### **Recommendation 10 (Scope-section 1.1)**

As noted in the contribution to the eWG, the EU continues to support the inclusion of the statement "It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)" in the scope, which would be in line with the Format for Codex Commodity Standards establishing that "This section should contain a clear, concise statement as to the food or foods to which the standard is applicable (...)".

#### **Recommendation 11 (Scope-section 1.2)**

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.

#### **Recommendation 12 (Scope-section 1.3)**

The EU agrees with the Chairs' recommendation.

As regards the wording in square brackets, the EU would prefer to use "**shall**" instead of "**should**" in order to ensure consistency with the terminology used in the labelling section of the Standard.

#### **Recommendation 14 (Labelling-introductory paragraph)**

The EU agrees with the Chairs' recommendation.

As noted in the contribution to the eWG, the EU is of the view that the Codex General Standard for the Labelling of Pre-packed Foods (CODEX STAN 1-1985) and the Guidelines on Nutrition Labelling (CAC/GL 2-1985) should be referenced in an introductory paragraph, in line with the approach followed in the Infant Formula Standard.

With regard to the inclusion of a reference to the applicability of the recommendations in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), in the EU a number of applications for authorisation of claims made on foods for infants and young children are pending. The EU cannot therefore provide its full views on the matter at this stage, since a decision has not yet been taken in relation to those applications. However, the EU finds the Chairs` proposal to refer to the Guidelines, as a reasonable compromise between different views in the eWG.

#### **Recommendation 15 (NRV for infants and young children)**

As noted in the contribution to the eWG, in the EU a number of applications for authorisation of claims made on foods for infants and young children are pending. The EU cannot therefore provide its full views on the revisit of nutrition claims at this stage, since a decision has not

yet been taken in relation to those applications. However, the EU agrees with the Chairs' recommendation that the progress of reviewing the Standard should not be delayed. A decision to develop NRVs for infants and young children may be taken, but such work is in principle not related at this stage to the finalisation of this Standard.

The EU agrees with the Chairs' proposal to maintain the status quo for nutrition and health claims i.e. the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in the relevant Codex Standards or national legislation.

#### **Recommendation 16 (Name of Product)**

With regard to section 9.1, 9.1.1, 9.1.2, 9.1.3, the EU agrees with the wording proposed by the Chairs.

With regard to section 9.1.4, as noted in the contribution to the eWG, the EU is supportive of retaining this provision in consistency with the Infant Formula Standard, provided that it specifically reflects that goat's milk can also be a source of protein for follow-up formula (i.e. "If cows' (or goats') milk is the only source of protein, the product may be labelled "Follow-Up Formula for older infants based on Cows' (or goats') Milk").

In light of the above, the EU prefers OPTION 1 for provision 9.1.4, which clearly indicates the only source of protein (such as cows'milk, goats'milk or soy) present in the product.

With regard to section 9.1.5, the EU can support use of the word "shall" for consistency with the Infant Formula Standard.

## **Recommendation 17 (List of ingredients)**

With respect to section 9.2.1, the EU agrees with the Chairs' proposal to delete the text [including optional ingredients] as it is already covered by the provision under section 9.2.1 and it is therefore redundant. The recommendation would also ensure consistency with the Infant Formula Standard, which is of great importance.

With respect to section 9.2.2, the EU is not convinced by the necessity to add the proposed text in square brackets, since it is not specifically mentioned in the Infant Formula Standard either. The EU would once again stress the importance to ensure consistency with the Infant Formula Standard, unless divergences are justified.

#### **Recommendation 18 (Declaration of Nutritive Value)**

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, both indications are useful: while nutrition information per 100 ml of the food ready for use is of most value to consumer, indication per 100 grams of the food as sold can be more relevant for health care professionals. Further to this, the proposed recommendation would also ensure consistency with the Infant Formula Standard.

#### **Recommendation 19 (Date Marking and Storage Instructions)**

The EU agrees with the Chairs' proposal to adopt any changes proposed at CCFL44 in order to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting.

#### **Recommendation 20 (Information for use)**

With respect to section 9.5.1, 9.5.2, 9.5.3, 9.5.4, 9.5.5, the EU agrees with the Chairs' recommendations which ensure clarity on the different requirements applicable to Follow-Up Formula for older infants.

With respect to section 9.5.6, the EU welcomes the proposal to delete the text "not to be used as a sole source of nutrition" and to keep the text "older infants should receive complementary foods in addition to the formula". As noted in the contribution to the eWG, both sentences convey the same message therefore keeping only the latter one which is more complete would be sufficient.

However, the EU continues to suggest including the following statement in section 9.5 of the Standard on Follow-Up formula for older infants: "the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs". As noted in the contribution to the eWG, a statement similar to above would stress the importance health care professionals' advice for deciding when to begin complementary feeding, including any exception to six months of age, taking into account individual infants' specific growth and development needs. It is corroborated by the Scientific Opinion of EFSA of 2009 on the appropriate age of introduction of complementary feeding (currently subject of review) and it would also ensure consistency with provision 8.6.4 of CODEX STAN 74-1981 for processed cereal-based foods for infants and young children and provision 10.2.4.1 of the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991), where the same statement is required.

## **Recommendation 21 (Additional Labelling Requirements)**

The EU 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.

With respect to section 9.6.4, the EU strongly supports the inclusion of the following text the in the provision, in line with EU legislation (Article 6(6)3rd paragraph of delegated Regulation (EU) 2016/127): "and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used". As noted in previous occasions, 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.

#### SCOPE AND LABELLING-YOUNG CHILDREN (12-36 MONTHS)

## **Recommendation 22 (Scope-section 1.1)**

As noted in the contribution to the eWG, the EU continues to support the inclusion of the statement "It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)" in the scope, which would be in line with the Format for Codex Commodity Standards establishing that "This section should contain a clear, concise statement as to the food or foods to which the standard is applicable (...)"

#### **Recommendation 23 (Scope-section 1.2)**

The EU can accept the Chairs' proposal that Section 1.2 of the Scope for follow-up formula for young children be expanded to reference the labelling and analytical requirements within the Standards.

#### **Recommendation 24 (Scope-section 1.3)**

The EU agrees with the Chairs' recommendation.

As regards the wording in square brackets, the EU would prefer to use "**shall**" instead of "**should**" in order to ensure consistency with the terminology used in the labelling section of the Standard

#### **Recommendation 26 (Labelling-introductory paragraph)**

The EU agrees with the Chairs' recommendation.

As noted in the contribution to the eWG, the EU is of the view that the Codex General Standard for the Labelling of Pre-packed Foods (CODEX STAN 1-1985) and the Guidelines on Nutrition Labelling (CAC/GL 2-1985) should be referenced in an introductory paragraph, in line with the approach followed in the Infant Formula Standard.

With regard to the inclusion of a reference to the applicability of the recommendations in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), in the EU a number of applications for authorisation of claims made on foods for infants and young children are pending. The EU cannot therefore provide its full views on the matter at this stage, since a decision has not yet been taken in relation to those applications. However, the EU finds the Chairs` proposal to refer to the Guidelines as a reasonable compromise between different views in the eWG.

## Recommendation 27 (NRV for infants and young children)

As noted in the contribution to the eWG, in the EU a number of applications for authorisation of claims made on foods for infants and young children is pending. The EU cannot therefore provide its full views on the revisit of nutrition claims at this stage, since a decision has not yet been taken in relation to those applications. However, the EU agrees with the Chairs' recommendation that the progress of reviewing the Standard should not be delayed. A

decision to develop NRVs for infants and young children may be taken, but such work is in principle not related at this stage to the finalisation of this Standard.

The EU agrees with the Chairs' proposal to maintain the status quo for nutrition and health claims i.e. the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in the relevant Codex Standards or national legislation.

## **Recommendation 28 (Name of Product)**

With regard to section 9.1, 9.1.1, 9.1.2, 9.1.3, the EU agrees with the wording proposed by the Chairs.

With regard to section 9.1.4, as noted in the contribution to the eWG, the EU is supportive of retaining this provision in consistency with the Infant Formula Standard, provided that it specifically reflects that goat's milk can also be a source of protein for follow-up formula (i.e. "If cows' (or goats') milk is the only source of protein, the product may be labelled 'name of product (for young children)' based on Cows' (or goats') Milk").

In light of the above, the EU prefers OPTION 1 for provision 9.1.4 which clearly indicates the only source of protein (such as cows'milk, goats'milk or soy) present in the product.

With regard to section 9.1.5, the EU can support use of the word "shall" for consistency with the Infant Formula Standard (and Section A of the Follow-Up Formula Standard).

## **Recommendation 29 (List of ingredients)**

With respect to section 9.2.1, the EU agrees with the Chairs' proposal to delete the text [**including optional ingredients**] as it is already covered by the provision under section 9.2.1 and it is therefore redundant.

With respect to section 9.2.2, the EU is not convinced by the necessity to add the proposed text in square brackets, since it is not specifically mentioned in the Infant Formula Standard either. The EU would once again stress the importance to ensure consistency with the Infant Formula Standard, unless divergences are justified.

#### **Recommendation 30 (Declaration of Nutritive Value)**

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.

The EU also agrees with the deletion of the words "per serving size" taking into account that the declaration of nutrients per serving size 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.

#### **Recommendation 31 (Date Marking and Storage Instructions)**

The EU agrees with the Chairs' proposal to adopt any changes proposed at CCFL44 in order to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting.

#### **Recommendation 32 (Information for use)**

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.

#### **Recommendation 33 (Additional labelling requirements)**

The EU agrees 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 Follow-Up Formula 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.

With respect to section 9.6.1 the EU supports the inclusion of the wording "including pictures of feeding bottles". Firstly, 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. Secondly, 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.

With respect to section 9.6.2, the EU strongly supports the inclusion of the following text the in the provision, in line with EU legislation (Article 6(6)3rd paragraph of delegated Regulation (EU) 2016/127): "and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used". As noted in previous occasions, 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.

For this reason explained before, the EU supports an additional labelling requirement that "The label shall have no text that might recommend or promote bottle feeding of the product".

#### **PRODUCT DEFINITIONS**

#### **Recommendation 34 (Definition for Follow-Up Formula for older infants)**

As noted in the contribution to the eWG, the EU would like to reiterate that Follow-Up Formula for older infants (6-12 months) and (Name of Product) for Young Children (12-36 months) can be considered as conceptually similar: they are liquid elements in the diversified diet of older infants and young children. While it is obvious that their role in the diet of infants and young children changes with time, as diets progressively diversify (i.e. the product's relative contribution to energy and nutrient requirements decreases with time), this does not mean that Follow-Up Formula for older infants are always completely different from (Name of Product) for Young Children and should therefore have a different definition, or a different name. If this approach had to be followed, then one would also have to provide different definitions/names for products for young children aged 12-18, 18-24, 24-36 months. This would be an endless exercise, and would create excessive confusion.

In light of the above the EU continues to support a broad and simpler definition, similar to the one present in the current Follow-Up Formula Standard, which would cover both products for older infants and for young children. By way of example, "Follow-up formula means a product intended for use as a liquid part of the progressively diversified diet for older infants, when complementary feeding is introduced, and for young children".

#### **Recommendation 35 (Definition for Follow-Up Formula for young children)**

As noted in the contribution to the eWG, the EU would like to reiterate that Follow-Up Formula for older infants (6-12 months) and (Name of Product) for Young Children (12-36 months) can be considered as conceptually similar: they are liquid elements in the diversified diet of older infants and young children. While it is obvious that their role in the diet of infants and young children changes with time, as diets progressively diversify (i.e. the product's relative contribution to energy and nutrient requirements decreases with time), this does not mean that Follow-Up Formula for older infants are always completely different from (Name of Product) for Young Children and should therefore have a different definition, or a different name. If this approach had to be followed, then one would also have to provide different definitions/names for products for young children aged 12-18, 18-24, 24-36 months. This would be an endless exercise, and would create excessive confusion.

In light of the above the EU continues to support a broad and simpler definition, similar to the one present in the current Follow-Up Formula Standard, which would cover both products for older infants and for young children. By way of example, "Follow-up formula means a product intended for use as a liquid part of the progressively diversified diet for older infants, when complementary feeding is introduced, and for young children".

As regards the concept of including the wording "when nutrient intakes may not be adequate to meet the nutritional requirements of young children" in the Standard, the EU continues to reiterate its concerns. As noted in previous occasions, this definition seems to imply that these products are necessary to tackle nutritional deficiencies: however, as EFSA noted in its advice 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. In addition, the fact that this element is not present in the definition of Follow-Up Formula for older infants further increases confusion, taking into account that the products can be considered as conceptually similar.

#### **PRODUCT NAMES**

## **Recommendation 36 (Name of product for older infants)**

The EU agrees with the Chairs' recommendation.

## **Recommendation 37 (Name of product for young children)**

As noted in previous occasions, the EU is of the view that different names for products for older infants and young children would give excessive recognition to (Name of Product) for Young Children.

The EU continues to agree with the Chairs that it is essential to ensure that products for older infants and products for young children are clearly distinguishable. However, this can be better achieved by including in the Standard a provision clearly requiring operators to ensure that this is the case, and specifying how that should be ensured, as it is recommended under sections 9.6.4 and 9.6.2.