

**European Union Comments**  
**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL**  
**DIETARY USES**

**Thirty-seventh Session**

**Bad Soden am Taunus, Germany, 23 – 27 November 2015**

**Agenda item 5**

**Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987) at Step 4**

**CX/NFSDU 15/37/5**

*European Union competence*  
*European Union vote*

The European Union (EU) would like to thank New Zealand, France and Indonesia for their work on document CX/NFSDU 15/37/5. On the basis of the on-going discussions in the EU on follow-up formula, the EU would like to offer the following preliminary comments.

**GENERAL COMMENTS**

**On follow-up formula for older infants**

The EU is of the view that the compositional requirements for follow-up formula for older infants should be consistent with those for infant formula unless differences are scientifically justified (e.g. iron levels). The EU is also of the view that the current revision of the compositional requirements of follow-up formula for older infants should take into account the most recent, relevant, scientific information available. In this respect, the EU would like to point to the Scientific Opinion of the European Food Safety Authority on the essential composition of infant and follow-on formulae which was issued last year (2014)<sup>1</sup>. This is the most recent systematic advice by a Codex recognized authoritative scientific body (RASB) on the composition of infant formula and follow-up formula for older infants.

In line with our preference for consistency in the compositional requirements for follow-up formula for older infants and those for infant formula, the EU considers that once agreement is reached in CCNFSDU on the compositional requirements for follow-up formula for older infants, efforts should be undertaken to ensure that the compositional requirements for infant formula are based on the same datasets used for follow-up formula for older infants. Such efforts should aim to a targeted revision of section 3 of CODEX Standard 72-1981 on Infant Formula and Formulas for special medical purposes intended for infants. It is important to underline that this targeted revision would be based on the agreed compositional requirements for follow-up formula for older infants - with scientifically justified differences as appropriate – and would not open other sections of the Infant Formula Standard.

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<sup>1</sup> <http://www.efsa.europa.eu/fr/efsajournal/doc/3760.pdf>

## **On follow-up formula for young children**

Bearing in mind previous discussions in CCNFSDU and in the relevant eWGs, the EU finds the approach proposed by the Chairs sensible and considers that it merits further consideration in CCNFSDU. In our view, this takes into account the difficulty to lay down specific compositional rules for follow-up formula for young children *per se*, and regional variability with respect to nutrients of concerns. Furthermore, it is in line with the scientific advice of EFSA (2014) whereby, "*formulae consumed during the first year of life can continue to be used by young children*" and with the consideration that the increased consumption of other foods in the diet of young children makes it unnecessary to require follow-up formula for young children to comply with all the requirements for follow-up formula for older infants.

The EU is of the view that if minimum compositional requirements are to be set for follow-up formulae for young children, the main focus should be on those nutrients whose consumption is inadequate on a global scale. This is all the more valid, given that, in any case, the eWG Chairs propose to leave to the discretion of national authorities the mandatory addition of other nutrients to meet the specific needs of their population.

In this context, the EU notices that there is no known global inadequate intake on a global scale for some of the listed nutrients proposed by the eWG Chairs for mandatory addition. The EU would therefore like to seek further clarification on the rationale underpinning the proposed nutrients.

### **SPECIFIC COMMENTS**

**The EU has a number of suggestions for re-drafting to the text as indicated below.**

<b>Section 2, paragraph 2.1.1</b>
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The following redrafting is proposed:

2.1.1 Follow-up formula means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

- ~~{a) the a liquid part of the **progressively diversified** diet for older infants, when complementary feeding is introduced; and  
b) a liquid part of the progressively diversified diet of **for** young children.}~~

#### Rationale:

The EU is of the view that follow-up formula for older infants (6-12 months) and young children (12-36 months) are conceptually similar: they are liquid elements in the diversified diet of older infants and young children. For this reason the EU wonders whether the text proposed by the eWG Chairs, which lists two different product categories under letters (a) and (b), would give an unnecessary and unjustified recognition to the difference between the two product categories. The EU would support a broad and simpler definition for follow-up formula, similar to the one present in the current Standard, which would also avoid repetitions.

The EU would, in addition, like to note that there is no reason to qualify infants as "older", given that a reference to introduction of complementary feeding is included.

### **Section 2, paragraph 2.1.2**

The following redrafting is proposed:

~~{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}.~~

OR

~~{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 [and sale] in the country where the product is sold}.~~

#### Rationale:

The EU would support the first option presented in document CX/NFSDU 15/37/5, which mirrors the existing wording of point 2.1.2 of the Infant Formula Standard. The EU would like to seek clarification on the rationale for the changes proposed in the second option, and on why these should be relevant for follow-up formula and not for infant formula.

### **Section 2, paragraph 2.2.2**

The following redrafting is proposed:

~~2.2.2 [Older infants means persons from the age of 6 months and not more than 12 months of age.]~~

#### Rationale:

The EU is of the view that there is no need to introduce a definition of "older infant" given that the definition proposed specifically refers to the introduction of complementary feeding.

### **Section 2, paragraph 2.2.3**

A minor editorial is proposed:

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

### **Section 3, paragraph, 3.1.1**

The following redrafting is proposed:

3.1.1 Follow-up formula is a ~~{food} OR {product} prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, {based on} OR {consisting of}~~ milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been ~~{proved} OR {proven}~~ to be ~~{safe and}~~ suitable **for the feeding of infants, after the**

**introduction of complementary feeding, and for young children.** ~~{and nutritionally adequate} [to support growth and development] for [the intended age range] OR [older infants and young children]. infants from the 6th month on and for young children. [The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants~~ **after the introduction of complementary feeding** ~~and young children.]~~

OR

~~{Consumption of the formula should appropriately contribute to normal growth and development of the intended age range}.~~

Rationale:

The EU is of the view that the requirement under consideration should follow as much as possible the one established in the Infant Formula Standard (with adjustments where necessary).

In particular, the EU proposes deletion of the comma after the word "*thereof*". The reason for this is to ensure that the suitability requirement in the definition applies to both "*other ingredients*" and "*milk of cows or other animals or a mixture thereof*". In order to protect the health of infants and young children, it is important to ensure that all ingredients of formulae are suitable, including the animal protein source.