

## **WORKING DOCUMENT**

### **on the adoption of a delegated Regulation on processed cereal-based food and baby food pursuant to Article 11(1) of Regulation (EU) No 609/2013**

[Supporting Document for the meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health of 17 February 2015]

#### **Introduction**

Article 11(1) of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control<sup>1</sup> (the FSG Regulation) empowers the Commission to adopt specific compositional and information requirements by the means of delegated acts for the categories of foods covered by the Regulation.

This Working Document seeks the views of relevant NGOs and stakeholders on the different aspects that shall be covered by the future Commission delegated Regulation to be adopted pursuant to Article 11(1) of the FSG Regulation on processed cereal-based food and baby food.

The text included in this Working Document is based on the existing provisions of Commission Directive 2006/125/EC<sup>2</sup>. Minor updates on the provisions on labelling are foreseen, taking into account discussions carried out with Member States' experts, relevant NGOs and stakeholders so far.

This Working Document presents the recitals, Articles and Annexes that are considered for inclusion in the Commission delegated Regulation. As regards Articles and Annexes, the document also provides explanations of the different provisions.

This Working Document is aimed at facilitating the discussions on 17 February 2015 and is without prejudice to the final decision the Commission will take when adopting the delegated Regulation pursuant to Article 11(1) of the FSG Regulation.

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<sup>1</sup> Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control, OJ L 181, 29.6.2013, p. 35

<sup>2</sup> Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children, OJ L 339, 6.12.2006, p.16

## **A. RECITALS**

*The following text is being considered for the recitals that could be included in the delegated Regulation:*

Whereas:

- (1) Commission Directive 2006/125/EC<sup>3</sup> lays down, under the framework of Directive 2009/39/EC of the European Parliament and of the Council<sup>4</sup>, harmonised rules on processed cereal-based food and baby food.
- (2) In the context of the revision of the legislation on foodstuffs intended for particular nutritional uses, Regulation (EU) 609/2013 repeals Directive 2009/39/EC and Directive 2006/125/EC and lays down general compositional and information requirements for different categories of foods including processed cereal-based food and baby food. The Regulation also foresees the establishment of specific compositional and information requirements for processed cereal-based food and baby food by means of delegated acts, taking into account the provisions of Directive 2006/125/EC, by 20 July 2015.
- (3) Processed cereal-based food and baby food are used by infants and young children as part of a diversified diet and do not constitute the sole source of nourishment of infants and young children.
- (4) The essential composition of processed cereal-based food and baby food should be appropriate for the nutritional requirements of infants and young children in good health as established by generally accepted scientific data.
- (5) There is a great variety of processed cereal-based food and baby food, which reflects the widely varied diet of infants being weaned and young children owing to social and cultural circumstances existing in the Union. It is therefore not appropriate to lay down detailed compositional rules for these foods.
- (6) The nature and destination of processed cereal-based food and baby food require the establishment of a number of specific mandatory compositional requirements and other restrictions concerning the content of vitamins, minerals and other nutrients present in the product or added to it. Such rules should be based on those of Directive 2006/125/EC, given that they have ensured an adequate framework for processed cereal-based food and baby food so far and should be updated in the future depending on scientific and technological developments.
- (7) Commission Directive 2006/125/EC lays down specific requirements on the use of pesticides in products intended for the production of and on pesticide residues in processed cereal-based food and baby food, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997<sup>5</sup> and 4 June 1998<sup>6</sup>.

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<sup>3</sup> Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p.16)

<sup>4</sup> Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.05.2009, p.21)

<sup>5</sup> Opinion of the Scientific Committee for Food on a maximum residue limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children (expressed on the 19th September 1997)

<sup>6</sup> Further advice on the opinion of the Scientific Committee for Food expressed on the 19 September 1997 on a Maximum Residue Limit (MRL) of 0.01 mg/Kg for pesticides in foods intended for infants and young children (adopted by the SCF on 4 June 1998)

Because of the scientific uncertainty at that time as to the adequacy of existing acceptable daily intake (ADI) values of pesticides and pesticide residues for the protection of the health of infants and young children, it was considered appropriate to adopt, on the basis of the precautionary principle, a very low common limit for all pesticides. This very low common limit was fixed at 0,01 mg/kg which was in practice the limit of quantification. In addition, more severe limitations were set in the case of a small number of pesticides or metabolites of pesticides for which even a maximum residue level (MRL) of 0,01 mg/kg might, under worst-case intake conditions, lead to an exposure exceeding the ADI for infants and young children. This was the case for pesticides or metabolites of pesticides with an ADI lower than 0,0005 mg/kg body weight/day.

- (8) Regulation (EU) No 609/2013 empowers the Commission to adopt specific requirements on the use of pesticides in products intended for the production of the food covered by the Regulation, including processed cereal-based food and baby food, and on pesticide residues in such food, when establishing specific requirements for the foods covered by the Regulation, by means of delegated acts. The Regulation also requires that the specific requirements on pesticides for the categories of food for infants and young children under its scope, including processed cereal-based food and baby food, should be updated regularly and include, inter alia, provisions to restrict the use of pesticides as much as possible. A restriction on, or a prohibition of use would however not necessarily guarantee that food covered by the Regulation, including food for infants and young children, is free from pesticides, since some pesticides are persistent in the environment and their residues can be found in the food. For this reason Regulation (EU) No 609/2013 foresees that the MRLs in such food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.
- (9) With respect to processed cereal-based food and baby food, Regulation (EU) No 609/2013 foresees that restrictions on and prohibitions of certain pesticides equivalent to those currently established in the Annexes to Directive 2006/125/EC should be taken into account in the delegated act laying down requirements for these foods. When updating such restrictions and prohibitions, particular attention should be paid to certain substances of concern, with the objective to ultimately avoid their use.
- (10) Exchanges between the Commission and the European Food Safety Authority ('the Authority') have revealed that a thorough update of the rules on pesticides in foods for infants and young children would require a significant amount of time given that a comprehensive evaluation should be carried out on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children as such. For this reason, and in order to respect the provisions of Regulation (EU) No 609/2013 whereby specific compositional and information requirements for processed cereal-based food and baby food should be established by 20 July 2015, the relevant existing requirements of Directive 2006/125/EC should, at this stage, be maintained as they are. These requirements should be updated in the future taking into account the opinion of the Authority on the matter.

- (11) Processed cereal-based food and baby food should comply with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>7</sup>. In order to take account of the specific nature of processed cereal-based food and baby food, this Regulation lays down additions and exceptions to those general rules, where appropriate.
- (12) The provision of food information on all the particulars that are necessary to ensure the appropriate use of processed cereal-based food and baby food should be mandatory for this type of food, including information on the age from which the product may be used.
- (13) The nutrition declaration for processed cereal-based food and baby food is important to guarantee the appropriate use of the products. For this reason, in order to provide more complete information, all processed cereal-based food and baby food should provide the mandatory nutrition declaration, irrespective of the package size, and the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011.
- (14) Article 30(2) of Regulation (EU) No 1169/2011 limits the particulars that can be included on a voluntary basis in the nutrition declaration for food. The Annex of Regulation (EU) No 609/2013 lists a series of nutrients that may be added to processed cereal-based food and baby food and some of these are not covered by Article 30(2) of Regulation (EU) No 1169/2011. In order to ensure legal clarity, it should be clarified that the nutrition declaration for processed cereal-based food and baby food may include indication on nutrients which may be added to the products in question and are listed in Annex of Regulation (EU) No 609/2013.
- (15) Healthy infants and young children have different nutritional needs than adults. Expression of nutrition information on the energy value and the amount of nutrients of processed cereal-based food and baby food as percentage of daily reference intake values set out for the general adult population in Regulation (EU) No 1169/2011 would therefore mislead consumers and should not be allowed. For this reason, and in order to ensure comparisons with other foods that can be included in the diet of infants and young children together with complementary feeding, these products should be allowed to express the amounts of vitamins and minerals as a percentage of specific reference intakes that are appropriate for the age group, provided that the substances are present in significant amounts in the product.
- (16) Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>8</sup> requires Member States to enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. In this context, the competent authorities of Member States may request at any time the food business operator placing processed cereal-based food and baby food on the market to produce all relevant elements and data establishing compliance with this Regulation.
- (17) Adequate transitional measures should be foreseen to enable food business operators to adapt to the requirements of this Regulation,

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<sup>7</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ L 304, 22.11.2011, p.18

<sup>8</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p.1

## **B. ARTICLES**

*The following text is being considered for the Articles that could be included in the delegated Regulation. Explanations are provided in the boxes.*

### **CHAPTER 1**

#### **SUBJECT MATTER, SCOPE AND PLACING ON THE MARKET**

##### **Article 1**

##### **Subject matter and scope**

*[cf. Article 1 of Directive 2006/125/EC]*

This delegated Regulation lays down specific requirements for processed-cereal based food and baby food, pursuant to Article 11(1) of Regulation (EU) No 609/2013.

→ As it is the case today in Directive 2006/125/EC, this provision clearly states the subject matter and scope of the delegated Regulation.

##### **Article 2**

##### **Placing on the market**

*[cf. Article 3 of Directive 2006/125/EC]*

Processed-cereal based food and baby food may be marketed within the Union only if they comply with this Regulation.

→ This provision repeats text already present in Directive 2006/125/EC. It establishes the requirement whereby only products complying with the delegated Regulation may be marketed within the EU.

### **CHAPTER 2**

#### **REQUIREMENTS ON COMPOSITION AND PESTICIDES**

##### **Article 3**

##### **Composition requirements for processed cereal-based food and baby food**

1. Processed cereal-based food and baby food shall be manufactured from ingredients whose suitability for infants and young children has been established by generally accepted scientific data. *[cf. Article 4 of Directive 2006/125/EC]*
2. Processed cereal-based food shall comply with the compositional criteria specified in Annex I. *[cf. Article 5(1) of Directive 2006/125/EC]*
3. Baby food which is described in Annex II shall comply with the compositional criteria specified therein. *[cf. Article 5(2) of Directive 2006/125/EC]*

→ This provision repeats text currently present in Directive 2006/125/EC and establishes the requirement on the suitability of all ingredients used in processed cereal-based food and baby food.

In addition, the delegated Regulation will need to lay down specific compositional requirements for processed cereal-based food and baby food. As it is the case in Directive 2006/125/EC, the provisions above foresee that processed cereal-based food and baby food shall comply with the detailed provisions laid down in the relevant Annexes.

**Article 4**  
**Requirements on pesticides**  
*[cf. Article 7 of Directive 2006/125/EC]*

1. For the purposes of this Article, ‘pesticide residue’ means the residue in processed cereal-based and baby food of a plant protection product, as referred to in Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>9</sup>, including its metabolites and products resulting from its degradation or reaction.

2. Processed cereal-based and baby food shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg.

Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

3. The pesticides listed in Annex V shall not be used in agricultural products intended for the production of processed cereal-based and baby food.

However, for the purpose of controls:

(a) pesticides listed in Table 1 of Annex V are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress;

(b) pesticides listed in Table 2 of Annex V are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

4. By way of derogation from paragraph 2, for the pesticides listed in Annex VI, the maximum residue levels specified therein shall apply.

5. The levels referred to in paragraphs 2, 3 and 4 shall apply to the products ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

➔ The provisions in this Article maintain the existing provisions on pesticides and pesticides residues of Directive 2006/125/EC. The FSG Regulation requires that rules on pesticides in processed cereal-based and baby food are updated regularly and include, *inter alia*, provisions to restrict the use of pesticides as much as possible (Article 11(1)(b)). Recitals mention that MRLs should be set at the lowest achievable level and that restrictions equivalent to those laid down in Directive 2006/125/EC should be taken into account in the delegated act.

<sup>9</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, p. 1

Exchanges between the Commission and EFSA have revealed that a thorough update of the rules on pesticides in foods for infants and young children would require a significant amount of time given that a comprehensive evaluation should be carried out on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children as such. For this reason, and in order to respect the provisions of Regulation (EU) No 609/2013 whereby specific compositional and information requirements for processed cereal-based and baby food should be established by 20 July 2015, the relevant existing requirements of Directive 2006/125/EC should, at this stage, be maintained as they are. At the same time, EFSA will be requested to provide a full scientific assessment on the matter so that the rules are updated in the future based on the latest scientific advice.

### CHAPTER 3 REQUIREMENTS ON FOOD INFORMATION

#### Article 5 Specific requirements on labelling, presentation and advertising

1. Unless otherwise specified in this Regulation, processed cereal-based food and baby food shall comply with the requirements laid down in Regulation (EU) No 1169/2011.

→ This **new** paragraph would generally clarify the relation between the FIC Regulation and this delegated Regulation with respect to food information.

2. In addition to the particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for processed cereal-based food and baby food:

- (a) a statement as to the appropriate age from which the product may be used, regard being had to its composition, texture or other particular properties; [*cf. Article 8(1)(a) of Directive 2006/125/EC*]
- (b) information as to the presence of gluten if the indicated age from which the product may be used is below six months; [*cf. Article 8(1)(b) of Directive 2006/125/EC*]
- (c) Instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions. [*cf. Article 8(1)(e) of Directive 2006/125/EC*]

The age referred to in letter (a) shall not be less than four months for any product. Products recommended for use from the age of four months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise; [*cf. Article 8(1)(a) of Directive 2006/125/EC*]

→ This paragraph repeats some of the existing provisions of Directive 2006/125/EC. In letter (b), a change is foreseen to increase legal clarity. Only indication of the presence of gluten is foreseen. Indication of the absence of gluten is covered by horizontal rules laid down in Regulation (EU) No 828/2014.

3. Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall apply to all mandatory particulars for processed cereal-based food and baby food.

→ This **new** paragraph is aimed at ensuring that rules on font size in the FIC Regulation would apply to all mandatory particulars required for processed cereal-based food and baby food (and not only those foreseen in FIC).

## **Article 6**

### **Specific requirements on the nutrition declaration**

1. The mandatory nutrition declaration for processed cereal-based food and baby food shall include, in addition to the particulars listed in Article 30(1) of Regulation (EU) No 1169/2011, the amount of each mineral substance and of each vitamin listed in Annex I and Annex II respectively and present in the product, with the exception of sodium. *[cf. Article 8(1)(c) and (d) of Directive 2006/125/EC]*

→ This paragraph clarifies that the mandatory nutrition declaration for processed cereal-based food and baby food shall include all the nutrients required by FIC as well as other specific nutrients whose indication is useful for the intended use of the product (as currently foreseen by Directive 2006/125/EC). In line with the rules of FIC, Indication of sodium is not required given that salt is indicated.

2. The content of the mandatory nutrition declaration referred to in paragraph 1 may be supplemented, in addition to the particulars listed in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, with an indication of the amounts of any of the nutrients listed in Annex of Regulation (EU) No 609/2013, provided that such indication is not covered by the provisions of paragraph 1. *[cf. Article 8(2)(a) of Directive 2006/125/EC]*

→ The paragraph repeats an existing provision of Directive 2006/125/EC.

3. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the particulars included in the nutrition declaration for processed cereal-based food and baby food shall not be repeated on the labelling.

→ This **new** paragraph is aimed at avoiding that the nutrition declaration (or parts of it) is repeated front of pack given that this kind of labelling would not be appropriate for processed cereal-based food and baby food.

4. Article 16(3) of Regulation No 1169/2011 shall not apply to processed cereal-based food and baby food in packaging or containers the largest surface of which has an area of less than 25 cm<sup>2</sup>.

→ This **new** paragraph is aimed at guaranteeing that all processed cereal-based food and baby food provide the nutrition declaration, irrespective of the package size (as it is the case today).

5. Without prejudice to the provisions of paragraph 7 of this Article, Article 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all nutrients included in the nutrition declaration for processed cereal-based food and baby food.

→ This **new** paragraph is aimed at ensuring that the requirements of the FIC Regulation on calculation, expression and presentation of the nutrition declaration apply to all the nutrients in the nutrition declaration for processed cereal-based food and baby food (and not only those covered by the FIC Regulation). In its absence, legal uncertainty would exist on certain nutrients (e.g. choline). It should be read together with paragraph 7 which lays down specific requirements on the order of presentation of nutrients in the nutrition declaration.

6. By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of processed cereal-based food and baby food



shall not be expressed as a percentage of the reference intakes set out in Annex XIII of Regulation (EU) No 1169/2011.

In addition to the form of expression referred to in Article 32(2) of Regulation (EU) No 1169/2011, the declaration on vitamins and minerals listed in Annex IV may be expressed as a percentage of the reference intakes set out therein in relation to per 100 g or per 100 ml of the food. Where no minimum levels are set for those vitamins and minerals in Annex I or Annex II, the expression as a percentage of the reference intakes shall be allowed provided that the quantities in the product are at least equal to 15% of the reference intakes laid down in Annex IV. [cf. Article 8(2)(b) of Directive 2006/125/EC]

→ The first part of this paragraph is **new**. It is aimed at derogating from the FIC Regulation that lays down rules for the expression of nutrition information as a percentage of reference intakes for adults laid down therein (as this would mislead parents and caregivers taking into account that processed cereal-based food and baby food are intended for infants and young children).

The second part is aimed at maintaining the status quo as laid down in Directive 2006/125/EC and allowing processed cereal-based foods and baby foods to additionally express amounts of vitamins and minerals as a percentage of specific reference intakes for infants and young children, as laid down in the delegated Regulation.

7. The particulars included in the nutrition declaration for processed cereal-based food and baby food that are not listed in Annex XV of Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV of Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented at the end of the nutrition declaration.

→ These **new** paragraphs are aimed at ensuring that the presentation of the nutrition declaration for processed cereal-based food and baby food follows the format set out in the FIC Regulation but taking into account the additional obligations required in the delegated Regulation for processed cereal-based food and baby food.

## CHAPTER 4 FINAL PROVISIONS

### Article 7 Entry into force

This Regulation shall enter into force on the [...] day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [3 years after entry into force]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

→ This provision establishes the deferred application of the delegated Regulation in order to give sufficient time to operators to adapt to the new requirements laid down therein.

## **C. ANNEXES**

*The following text is being considered for the Annexes that could be included in the delegated Regulation:*

### **ANNEX I ESSENTIAL COMPOSITION OF PROCESSED CEREAL-BASED FOOD FOR INFANTS AND YOUNG CHILDREN [cf. Annex I of Directive 2006/125/EC]**

→ This Annex transfers the requirements of Annex I of Directive 2006/125/EC. In Directive 2006/125/EC cross-references were made to the different paragraphs of the definition of processed cereal-based foods to describe the different product categories. Taking into account that the definition of processed cereal-based food is now given in the FSG Regulation, for the sake of legal clarity, the entire definitions are always repeated here.

In addition, a minor change is introduced in the introductory sentence, to ensure consistency with language used in the FIC Regulation (e.g. Article 31(3))

The requirements concerning nutrients refer to the food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

#### **1. CEREAL CONTENT**

Processed cereal-based food is prepared primarily from one or more milled cereals and/or starchy root products.

The amount of cereal and/or starchy root shall not be less than 25 % of the final mixture on a dry weight for weight basis.

#### **2. PROTEIN**

2.1. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid and rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, the protein content shall not exceed 1,3 g/100 kJ (5,5 g/100 kcal).

2.2. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the added protein shall not be less than 0,48 g/100 kJ (2 g/100 kcal).

2.3. For biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0,36 g/100 kJ (1,5 g/100 kcal).

2.4. The chemical index of the added protein shall be equal to at least 80 % of that of the reference protein (casein as defined in Annex III), or the protein efficiency ratio (PER) of the protein in the mixture shall be equal to at least 70 % of that of the reference protein. In all cases, the addition of amino acids shall be permitted solely for the purpose of improving the

nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

### **3. CARBOHYDRATES**

3.1. If sucrose, fructose, glucose, glucose syrups or honey are added to simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids and rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids:

- the amount of added carbohydrates from these sources shall not exceed 1,8 g/100 kJ (7,5 g/100 kcal),
- the amount of added fructose shall not exceed 0,9 g/100 kJ (3,75 g/100 kcal).

3.2. If sucrose, fructose, glucose syrups or honey are added to cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid:

- the amount of added carbohydrates from these sources shall not exceed 1,2 g/100 kJ (5 g/100 kcal),
- the amount of added fructose shall not exceed 0,6 g/100 kJ (2,5 g/100 kcal).

### **4. LIPIDS**

4.1. For simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids and rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, the lipid content shall not exceed 0,8 g/100 kJ (3,3 g/100 kcal).

4.2. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the lipid content shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal). If the lipid content exceeds 0,8 g/100 kJ (3,3 g/100 kcal):

- the amount of lauric acid shall not exceed 15 % of the total lipid content,
- the amount of myristic acid shall not exceed 15 % of the total lipid content,
- the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1 200 mg/100 kcal).

### **5. MINERALS**

#### **5.1. Sodium**

- sodium salts may only be added to processed cereal-based food for technological purposes,
- the sodium content of processed cereal-based food shall not exceed 25 mg/100 kJ (100 mg/100 kcal).

#### **5.2. Calcium**

5.2.1. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal).

5.2.2. For rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

## 6. VITAMINS

6.1. For processed cereal-based food, the amount of thiamin shall not be less than 25 µg/100 kJ (100 µg/100 kcal).

6.2. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
<b>Vitamin A (µg RE) <sup>(1)</sup></b>	14	43	60	180
<b>Vitamin D (µg) <sup>(2)</sup></b>	0,25	0,75	1	3

<sup>(1)</sup> RE = all trans retinol equivalents.

<sup>(2)</sup> In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

These limits shall also be applicable if vitamins A and D are added to other processed cereal-based foods.

## 7. MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED

The requirements concerning nutrients refer to the products ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions, except for potassium and calcium for which the requirements refer to the product as sold.

Nutrient	Maximum per 100 kcal
Vitamin A (µg RE)	180
Vitamin E (mg α-TE) <sup>(1)</sup>	3
Vitamin D (µg)	3
Vitamin C (mg)	12,5/25 <sup>(2)</sup>
Thiamin (mg)	0,5
Riboflavin (mg)	0,4

Niacin (mg NE) <sup>(3)</sup>	4,5
Vitamin B6 (mg)	0,35
Folic acid (µg)	50
Vitamin B12 (µg)	0,35
Pantothenic acid (mg)	1,5
Biotin (µg)	10
Potassium (mg)	160
Calcium (mg)	80/180 <sup>(4)</sup> /100 <sup>(5)</sup>
Magnesium (mg)	40
Iron (mg)	3
Zinc (mg)	2
Copper (µg)	40
Iodine (µg)	35
Manganese (mg)	0,6

<sup>(1)</sup> α-TE = d-α-tocopherol equivalent.

<sup>(2)</sup> Limit applicable to products fortified with iron.

<sup>(3)</sup> NE = Niacin equivalents = mg nicotinic acid + mg tryptophan/60.

<sup>(4)</sup> Limit applicable to simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids, and cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid.

<sup>(5)</sup> Limit applicable to rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids

**ANNEX II**  
**ESSENTIAL COMPOSITION OF BABY FOOD FOR INFANTS AND YOUNG CHILDREN**

*[cf. Annex II of Directive 2006/125/EC]*

➔ A minor change is introduced in the introductory sentence, to ensure consistency with language used in the FIC Regulation (e.g. Article 31(3))

The requirements concerning nutrients refer to the products ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

## **1. PROTEIN**

1.1. If meat, poultry, fish, offal or other traditional source of protein are the only ingredients mentioned in the name of the product, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
- the total protein from the named sources shall not be less than 1,7 g/100 kJ (7 g/100 kcal).

1.2. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal, then:

- the named poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 % by weight, of total named protein sources,
- the protein from the named sources shall not be less than 1 g/100 kJ (4 g/100 kcal).

1.3. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
- the protein from the named sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),
- the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.4. If cheese is mentioned together with other ingredients in the name of a savoury product, whether or not the product is presented as a meal, then:

- the protein from the dairy sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),
- the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.5. If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.6. Sauces presented as an accompaniment to a meal shall be exempt from the requirements of points 1.1 to 1.5 inclusive.

1.7. Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2,2 g dairy protein/100 kcal. All other sweet dishes shall be exempt from the requirements in 1.1 to 1.5.

1.8. The addition of amino acids shall be permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

## **2. CARBOHYDRATES**

The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:

- 10 g/100 ml for vegetable juices and drinks based on them,
- 15 g/100 ml for fruit juices and nectars and drinks based on them,
- 20 g/100 g for fruit-only dishes,
- 25 g/100 g for desserts and puddings,
- 5 g/100 g for other non-milk-based drinks.

## **3. FAT**

3.1. For products referred to in point 1.1:

If meat or cheese are the only ingredients or are mentioned first in the name of a product, the total fat in the product from all sources shall not exceed 1,4 g/100 kJ (6 g/100 kcal).

3.2. For all other products, the total fat in the product from all sources shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal).

## **4. SODIUM**

4.1. The final sodium content in the product shall be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100 g. However if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product shall not be more than 70 mg/100 kJ (300 mg/100 kcal).

4.2. Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.

## 5. VITAMINS

### Vitamin C

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product shall be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100 g.

### Vitamin A

In vegetable juices, the final content of vitamin A in the product shall be not less than 25 µg RE/100 kJ (100 µg RE/100 kcal).

Vitamin A shall not be added to other baby food.

### Vitamin D

Vitamin D shall not be added to baby food.

## 6. MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED

The requirements concerning nutrients refer to the products ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions, except for potassium and calcium for which the requirements refer to the product as sold.

Nutrient	Maximum per 100 kcal
Vitamin A (µg RE)	180 <sup>(1)</sup>
Vitamin E (mg α-TE)	3
Vitamin C (mg)	12,5/25 <sup>(2)</sup> /125 <sup>(3)</sup>
Thiamin (mg)	0,25
Riboflavin (mg)	0,4
Niacin (mg NE)	4,5
Vitamin B6 (mg)	0,35
Folic acid (µg)	50
Vitamin B12 (µg)	0,35
Pantothenic acid (mg)	1,5
Biotin (µg)	10
Potassium (mg)	160
Calcium (mg)	80
Magnesium (mg)	40
Iron (mg)	3
Zinc (mg)	2
Copper (µg)	40



Iodine ( $\mu\text{g}$ )	35
Manganese (mg)	0,6
<sup>(1)</sup> In accordance with the provisions of point 5 <sup>(2)</sup> Limit applicable to products fortified with iron. <sup>(3)</sup> Limit applicable to fruit-based dishes, fruit juices, nectars and vegetable juices.	

**ANNEX III**  
**AMINO ACID COMPOSITION OF CASEIN**  
*[cf. Annex III of Directive 2006/125/EC]*

	(g per 100 g of protein)
Arginine	3,7
Cystine	0,3
Histidine	2,9
Isoleucine	5,4
Leucine	9,5
Lysine	8,1
Methionine	2,8
Phenylalanine	5,2
Threonine	4,7
Tryptophan	1,6
Tyrosine	5,8
Valine	6,7

**ANNEX IV**  
**DAILY REFERENCE INTAKES FOR VITAMINS AND MINERALS FOR FOOD**  
**INTENDED FOR INFANTS AND YOUNG CHILDREN**  
*[cf. Annex V of Directive 2006/141/EC]*

Nutrient	Reference intake
Vitamin A	(µg) 400
Vitamin D	(µg) 7
Vitamin E	(mg TE) 5
Vitamin K	(µg) 12
Vitamin C	(mg) 45
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,7
Niacin	(mg) 7
Vitamin B6	(mg) 0,7
Folate	(µg) 125
Vitamin B12	(µg) 0,8
Pantothenic acid	(mg) 3
Biotin	(µg) 10
Calcium	(mg) 550
Phosphorus	(mg) 550
Potassium	(mg) 1 000
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(µg) 80
Selenium	(µg) 20
Copper	(mg) 0,5
Magnesium	(mg) 80
Manganese	(mg) 1,2

➔ This Annex updates Annex V of Directive 2006/125/EC on the basis of Annex VII of Directive 2006/141/EC.

**ANNEX V**

**PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION  
INTENDED FOR THE PRODUCTION OF PROCESSED CEREAL-BASED FOOD  
AND BABY FOOD**

*[cf. Annex VII of Directive 2006/125/EC]*

*Table 1*

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

*Table 2*

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin

**ANNEX VI**

**SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES  
OF PESTICIDES IN PROCESSED CEREAL-BASED FOOD AND BABY FOOD**

*[cf. Annex VI of Directive 2006/125/EC]*

<b>Chemical name of the substance</b>	<b>Maximum residue level (mg/kg)</b>
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006