



EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10355/2015
(POOL/E4/2015/10355/10355-EN.doc)
[...] (2015) XXX draft

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for processed cereal-based food and baby food

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control¹ repeals Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses² from 20 July 2016. Article 11 of the Regulation empowers the European Commission to adopt delegated acts laying down specific compositional and information requirements for the foods under its scope. These delegated acts shall be adopted by 20 July 2015. The relevant foods are:

- Infant formula and follow-on formula;
- Processed cereal-based food and baby food;
- Food for special medical purposes;
- Total diet replacement for weight control.

Recital 27 of the Regulation requires the Commission to take into account, when adopting such rules, Commission Directives 1996/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction³, 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes⁴, 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children⁵ and 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae⁶, which lay down rules for the abovementioned foods today.

Article 20(4) of the Regulation foresees that the existing Commission Directives are repealed from the date of application of the delegated acts adopted by the Commission.

This delegated Regulation transfers the existing rules of Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children under the new framework of Regulation (EU) No 609/2013 and updates them where relevant on the basis of the consultations described in point 2.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted in the context of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control⁷, which met on the subject on 15 May and 13 September 2013, and 18 February 2015.

NGOs and other stakeholders were consulted in the context of the Advisory Group on the Food Chain and Animal and Plant Health⁸, which held a Working Group on the subject on 17 February 2015. The possibility to provide written comments was

¹ OJ L 181, 29.6.2013, p. 35.

² OJ L 124, 20.5.2009, p. 21.

³ OJ L 55, 6.3.1996, p. 22.

⁴ OJ L 91, 7.4.1999, p. 29.

⁵ OJ L 339, 6.12.2006, p. 16.

⁶ OJ L 401, 30.12.2006, p. 1.

⁷ Reference E02893 in the Register of Commission Expert Groups and other similar entities.

⁸ Reference E00860 in the Register of Commission Expert Groups and other similar entities.

granted to all interested parties and comments were taken into account where relevant. Bilateral meetings were also held with all interested parties, as appropriate.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Regulation intends to incorporate the existing rules of Directive 2006/125/EC. Only minor adaptations are foreseen to the labelling rules, to ensure consistency with horizontal rules of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers⁹, taking into account the specificities of the products.

Following the request of Member States and food business operators, the Annex containing daily reference intakes for vitamins and minerals for food intended for infants and young children is updated to ensure consistency with rules applicable to infant formula and follow-on formula.

The application of the delegated Regulation is deferred to allow food business operators to adapt to the technical changes.

⁹ OJ L 304, 22.11.2011, p. 18.

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for processed cereal-based food and baby food

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009¹⁰, and in particular Article 11(1) thereof,

Whereas:

- (1) Commission Directive 2006/125/EC¹¹ lays down harmonised rules on processed cereal-based food and baby food in the framework of Directive 2009/39/EC of the European Parliament and of the Council¹².
- (2) Directives 2009/39/EC and 2006/125/EC are repealed by Regulation (EU) No 609/2013. That Regulation lays down general compositional and information requirements for different categories of food, including processed cereal-based food and baby food. The Commission has to adopt specific compositional and information requirements for processed cereal-based food and baby food, taking into account the provisions of Directive 2006/125/EC.
- (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) Owing to social and cultural circumstances existing in the Union, 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. It is therefore not appropriate to lay down detailed compositional rules for these foods.

¹⁰ OJ L 181, 29.6.2013, p. 35.

¹¹ 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).

¹² 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, 20.5.2009, p. 21).

- (6) The nature and destination of processed cereal-based food and baby food require the establishment of a number of specific compositional requirements and 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.
- (7) Pursuant to Regulation (EU) No 609/2013, the Commission has to adopt provisions restricting or prohibiting the use of pesticides and on pesticide residues in processed cereal-based food and baby food, taking account of those currently established in the Annexes to Directive 2006/125/EC. Adopting provisions that are in line with the current scientific knowledge requires a significant amount of time, given that a comprehensive evaluation has to be carried out by the European Food Safety Authority on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children. Taking into account the date of 20 July 2015 set by Regulation (EU) No 609/2013 for the adoption of this Delegated Regulation, the relevant existing requirements of Directive 2006/125/EC should, at this stage, be taken over. However, it is appropriate to use the terminology of Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹³.
- (8) Directive 2006/125/EC lays down specific requirements on the use of pesticides in products intended for the production of processed cereal-based food and baby food and on pesticide residues in such food, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997¹⁴ and 4 June 1998¹⁵.
- (9) A very low residue limit of 0,01 mg/kg for all pesticides is set on the basis of the precautionary principle. In addition, more severe limitations are set for 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 acceptable daily intake (ADI) for infants and young children.
- (10) A prohibition of the use of certain pesticides would not necessarily guarantee that processed cereal-based food and baby food are free from those pesticides, since some pesticides are persistent in the environment and their residues can be found in the food. For that reason, those pesticides are considered not to have been used if residues are below a certain level.
- (11) Processed cereal-based food and baby food have to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council¹⁶. In order to take account of the specific nature of processed cereal-based food and baby food, this

¹³ 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).

¹⁴ 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).

¹⁵ 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).

¹⁶ 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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Regulation should lay down additions and exceptions to those general rules, where appropriate.

- (12) Providing all information that is 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 that reason and in order to provide more complete information, the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011. In addition, the exemption provided for in point 18 of Annex V to Regulation (EU) No 1169/2011 should not apply and the nutrition declaration should be mandatory for all processed cereal-based food and baby food, irrespective of the package or container size.
- (14) Article 30(2) of Regulation (EU) No 1169/2011 contains a limited list of nutrients that may be included on a voluntary basis in the nutrition declaration for food. The Annex to Regulation (EU) No 609/2013 lists a series of substances that may be added to processed cereal-based food and baby food and some of them are not covered by Article 30(2) of Regulation (EU) No 1169/2011. In order to ensure legal clarity, it should be laid down explicitly that the nutrition declaration for processed cereal-based food and baby food may include such substances.
- (15) Healthy infants and young children have different nutritional needs than adults. The expression of nutrition information on the energy value and the amount of nutrients of processed cereal-based food and baby food as a percentage of daily reference intake values set out for the general adult population in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be allowed. For that reason, and in order to ensure comparisons with other foods that can be included in the diet of infants and young children, for processed cereal-based food and baby food it 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 Council¹⁷ 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 national competent authorities may request food business operators placing processed cereal-based food and baby food on the market to provide all relevant information considered necessary to demonstrate compliance with this Regulation.
- (17) In order to enable food business operators to adapt to the new requirements, this Regulation should apply from a date that is three years after its entry into force,

HAS ADOPTED THIS REGULATION:

¹⁷ 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.

Article 1
Placing on the market

Processed-cereal based food and baby food may only be placed on the market if they comply with this Regulation.

Article 2
Compositional requirements

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.
2. Processed cereal-based food shall comply with the compositional requirements set out in Annex I.
3. Baby food referred to in Annex II shall comply with the compositional requirements set out in that Annex.
4. The compositional requirements concerning nutrients set out in Annexes I and II shall apply to the processed cereal-based food and baby food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 3
Requirements on pesticides

1. For the purposes of this Article, 'residue' means the residue of an active substance as referred to in Article 2(2) of Regulation (EC) No 1107/2009 used in a plant protection product as referred to in Article 2(1) of that Regulation, including metabolites and products resulting from the degradation or reaction of that active substance.
2. Processed cereal-based food and baby food shall not contain residues at levels exceeding 0,01 mg/kg per active substance.
Those levels shall be determined by generally accepted standardised analytical methods.
3. By way of derogation from paragraph 2, for the active substances listed in Annex III, the maximum residue levels specified in that Annex shall apply.
4. Processed cereal-based food and baby food shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex IV have not been used.
However, for the purpose of checks, plant protection products containing the active substances listed in Annex IV are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg.
5. The levels referred to in paragraphs 2, 3 and 4 shall apply to the processed cereal-based food and baby food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 4
Specific requirements on food information

1. Unless otherwise provided in this Regulation, processed cereal-based food and baby food shall comply with Regulation (EU) No 1169/2011.
2. In addition to the mandatory 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. The stated age 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;
 - (b) information as to the presence of gluten if the indicated age from which the product may be used is below six months;
 - (c) instructions for appropriate preparation, where necessary, and a statement as to the importance of following those instructions.
3. Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall also apply to the additional mandatory particulars referred to in paragraph 2 of this Article.

Article 5
Specific requirements on the nutrition declaration

1. In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for processed cereal-based food and baby food shall include the amount of each mineral substance and of each vitamin listed in Annex I or Annex II to this Regulation respectively and present in the product, with the exception of sodium.
2. In addition to the information referred to in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, the content of the mandatory nutrition declaration for processed cereal-based food and baby food may be supplemented with the amounts of any of the substances listed in the Annex to Regulation (EU) No 609/2013, where such indication is not covered by paragraph 1 of this Article.
3. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for processed cereal-based food and baby food shall not be repeated on the labelling.
4. The nutrition declaration shall be mandatory for all processed cereal-based food and baby food, irrespective of the size of the largest surface of the packaging or container.
5. Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for processed cereal-based food and baby food.
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 to that Regulation.

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 in respect of the vitamins and minerals listed in Annex V to this Regulation may be expressed as a percentage of the reference intakes set out in that Annex 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 to this Regulation, the expression as a percentage of the reference intakes shall be allowed provided that the quantities present are at least equal to 15% of the reference intakes laid down in Annex V to this Regulation.

7. The particulars included in the nutrition declaration for processed cereal-based food and baby food that are not listed in Annex XV to 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 to 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 in the nutrition declaration after the last entry of that Annex.

Article 6

References to Directive 2006/125/EC

From [same date as in the second paragraph of Article 7] references to Directive 2006/125/EC in other acts shall be construed as references to this Regulation.

Article 7

Entry into force and application

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.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER