



Council of the
European Union

Brussels, 23 August 2017
(OR. en)

11715/17

DENLEG 66
AGRI 435
SAN 312

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	22 August 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	COM(2017) 438 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the exercise of the delegation conferred on the Commission pursuant to 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

Delegations will find attached document COM(2017) 438 final.

Encl.: COM(2017) 438 final



Brussels, 22.8.2017
COM(2017) 438 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**on the exercise of the delegation conferred on the Commission pursuant to 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**

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the delegation conferred on the Commission pursuant to 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

1. Introduction and legal basis

This report is intended to meet the obligation set for the Commission by Article 18(2) of 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 (hereinafter 'Food for Specific Groups Regulation')¹. Article 18(2) of the Food for Specific Groups Regulation requires the Commission to present to the European Parliament and to the Council a report on the exercise of the delegation conferred on the Commission by that Regulation. The report shall be drawn up not later than 9 months before the end of the 5-year period of the delegation, running from 19 July 2013. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

2. Exercise of the delegation

Article 18(2) of the Food for Specific Groups Regulation empowers the Commission to adopt delegated acts referred to in Article 11, Article 15(6) and Article 16(1) of that Regulation.

2.1. Article 11 of the Food for Specific Groups Regulation requires the Commission to lay down by the means of delegated acts specific requirements for the following categories of food: infant formula and follow-on formula; processed cereal-based food and baby food; food for special medical purposes; total diet replacement for weight control. Since the entry into force of the Food for Specific Groups Regulation, the Commission has adopted four delegated acts accordingly:

- a) a Commission Delegated Regulation (EU) 2016/127 supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding².

This legal act was adopted on 25 September 2015 with the objective to update the requirements for formulae intended for infants based on the latest scientific evidence.

¹ OJ L 181, 29.6.2013, p. 35.

² Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ L 25, 2.2.2016, p. 1.

It transferred the existing rules of Directive 2006/141/EC on infant formulae and follow-on formulae³ under the framework of the Food for Specific Groups Regulation and updated them as follows:

With respect to composition, the changes compared to Directive 2006/141/EC mainly related to specific amounts of certain macronutrients and micronutrients on the basis of the latest scientific evidence.

With respect to labelling, some changes were made, mainly 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 consumers (hereinafter 'the Food Information Regulation')⁴, taking into account the specificities of the products. Rules on nutrition and health claims on infant formula were updated taking into account the latest scientific advice. The notification procedure was maintained for infant formula and extended, in certain cases, to follow-on formula.

With regard to the rules on pesticides the relevant provisions of Directive 2006/141/EC were taken over. The Regulation will apply from 22 February 2020.⁵

- b) a Commission Delegated Regulation supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for processed cereal-based food and baby food⁶.

This Delegated Regulation was adopted by the Commission on 25 September 2015 and intended to transfer the existing rules of Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children⁷ under the framework of the Food for Specific Groups Regulation, with minor adaptations to the labelling rules, to ensure consistency with horizontal rules of the Food Information Regulation, taking into account the specificities of the products.

On 20 January 2016, the European Parliament adopted a Resolution⁸ objecting to the Delegated Regulation. The European Parliament expressed concerns on the compositional requirements for processed cereal-based food and baby food (in particular with respect to the sugar levels in the products) and the labelling and marketing requirements for these products (with respect to the provision of information on the introduction of complementary feeding before six months of age).

³ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1.

⁴ OJ L 304, 22.11.2011, p. 18.

⁵ Except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2021.

⁶ Commission Delegated Regulation (EU) .../...of 25.9.2015 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, C(2015) 6507 final.

⁷ 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.

⁸ P8_TA(2016)0015

- c) a Commission Delegated Regulation (EU) 2016/128 supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for food for special medical purposes⁹.

This legal act was adopted on 25 September 2015 with the objective to transfer the existing rules of Commission Directive 1999/21/EC on food for special medical purposes¹⁰ under the new framework of the Food for Specific Groups Regulation, to update them where relevant and to extend to food for special medical purposes for infants all rules on labelling, presentation, advertising and marketing applicable to formulae for healthy infants that are not contrary to the product's intended use. The Delegated Regulation also extended the rules on pesticides that apply to infant formula, follow-on formula, processed cereal-based food and baby food to food for special medical purposes for infants and young children.

With respect to labelling, changes made to the currently applicable Directive aimed at ensuring consistency with the Food Information Regulation, taking into account the specificities of the products, and increasing legal certainty on the intended use of the products. The use of nutrition and health claims on this type of food was prohibited. The Regulation will apply from 22 February 2019¹¹.

- d) a Commission Delegated Regulation supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for total diet replacement for weight control¹².

This Delegated Regulation was adopted by the Commission on 2 June 2017 and was submitted to the European Parliament and the Council for scrutiny. The main objective of the legal act is to update the existing rules on total diet replacement for weight control of Commission Directive 1996/8/EC on foods intended for use in energy-restricted diets for weight reduction¹³ and to include in its scope products placed on the market with very low energy content in order to ensure safety and suitability for all products intended to replace the totality of the daily diet.

⁹ Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes, OJ L 25, 2.2.2016, p. 30.

¹⁰ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, OJ L 91, 7.4.1999, p. 29.

¹¹ Except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

¹² Commission Delegated Regulation (EU) .../... of 2.6.2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement and weight control, C(2017)3664 final.

¹³ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction, OJ L 55, 6.3.1996, p. 22.

With respect to labelling, changes were made to ensure consistency with the Food Information Regulation, while taking into account the specificities of the products. Given the particular role of such foods in the diet of a specific group of consumers the Regulation limited the possibility to make nutrition claims and forbade the use of health claims on this type of foods. A notification procedure was introduced in order to facilitate efficient monitoring of these products. The Regulation will apply 5 years after its entry into force.

2.2. On the basis of Article 16(1) of the Food for Specific Groups Regulation the Commission adopted a Commission Delegated Regulation amending the Annex to the Food for Specific Groups Regulation as regards the list of substances that may be added to processed cereal-based food and baby food and to food for special medical purposes¹⁴.

This delegated act was adopted by the Commission on 10 April 2017 with the objective to update the Union list of substances that may be added to the specific categories of food to authorise the addition of ferrous bisglycinate, as a source of iron to processed cereal-based food and baby food and of calcium phosphoryl oligosaccharides, as a source of calcium to food intended for special medical purposes on the basis of EFSA's advice^{15,16} taking into account technical progress, scientific developments and protection of consumers' health.

2.3. On the basis of Article 15(6) of the Regulation a delegation of powers has been granted to add or remove a category of substances to the Annex to the Regulation, in order to take into account technical progress, scientific developments or the protection of consumer's health. So far, the Commission has not yet invoked this legal basis, as the relevant conditions have not applied yet.

3. Conclusion

The Food for Specific Groups Regulation has applied for a period of less than one year and it is not yet applicable in its entirety. So far, the Commission has adopted delegated acts on the specific compositional and information requirements for infant and follow-on formula and as regards requirements on information relating to infant and young child feeding and as regards the specific compositional and information requirements for food for special medical purposes. A delegated act on the specific compositional and information requirements for processed cereal-based food and baby food was objected to by the European Parliament. The

¹⁴ Commission Delegated Regulation (EU) 2017/1091 of 10.4.2017 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the list of substances that may be added to processed cereal-based food and baby food and to food for special medical purposes, OJ L 158, 21.6.2017, p. 5.

¹⁵ EFSA AFC Panel (EFSA Scientific Panel on food additives, flavourings, processing aids and materials in contact with food), Opinion related to Ferrous bisglycinate as a source of iron for use in the manufacturing of foods and in food supplements, The EFSA Journal (2006) 299, 1-17.

¹⁶ EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2016, Scientific Opinion on Calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium added for nutritional purposes to food, food supplements and foods for special medical purposes, EFSA Journal 2016;14(6):4488.

delegated act on the specific compositional and information requirements for total diet replacement for weight control was adopted by the Commission on 2 June 2017 and was submitted to the European Parliament and the Council for scrutiny. The delegated act amending the Annex to Regulation (EU) No 609/2013 as regards the list of substances that may be added to processed cereal-based food and baby food and to food for special medical purposes was adopted by the Commission on 10 April 2017.