EUROPEAN
COMMISSION

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[…](2017) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the lists of substances that may be added to processed cereal-based food and baby food and to food for special medical purposes

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 15 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[1] lays down requirements for the Union list, set out in the Annex to this Regulation, with respect to the substances that may be added to one or more categories of food referred to in Article 1(1), which 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.

In order to take into account the technical progress, scientific developments or the protection of consumers' health, Article 16(1) of the Regulation empowers the Commission to amend the Annex by the means of delegated act with respect to the addition of substances to the Union list.

In accordance with Article 22 of the Regulation, the Annex will apply from the date of application of the delegated acts concerned, adopted pursuant to Article 11.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the European Food Safety Authority (EFSA) on the matters. EFSA's Scientific Opinions on ferrous bisglycinate as a source of iron for use in the manufacturing of foods and in food supplements[2] and 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[3] constitute the scientific basis for this delegated Regulation.

Member States' experts were consulted in writing 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 control[4] between 30 August 2016 and 14 September 2016.

Written consultation with relevant stakeholders was carried out in the context of the Advisory Group on the Food Chain and Animal and Plant Health[5] between 16 September 2016 and 12 October 2016. No comments were received from stakeholders.

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1 OJ L 181, 29.6.2013, p. 35.

2 EFSA AFC Panel (EFSA Scientific Panel on food additives, flavourings, processing aids and materials in contact with food) related to Ferrous bisglycinate as a source of iron for use in the manufacturing of foods ad in food supplements, EFSA Journal 10.2903/j.efsa.2006.299.

3 EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2016, Scientific Opinions on Calcium phosphyoryl oligosaccharides (POs-Ca®) as a source of calcium added for nutritional purposes to food, food supplements and foods for special medical purposes, EFSA Journal doi: 10.2903/j.efsa.2016.4488.

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

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

3. LEGAL ELEMENTS OF THE DELEGATED ACT

With respect to the Union list of substances that may be added to the specific categories of food covered by the scope of Article 1(1) of Regulation (EU) No 609/2013, the Union list shall be updated in accordance with Article 16 of that Regulation 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 advices.

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(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, Commissions 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 953/2009[6], and in particular Article 16 thereof,

Whereas:

(1) The Annex to Regulation (EU) No 609/2013 establishes a Union list of substances that may be added to one or more of the categories of food referred to in Article 1(1). In accordance with Article 22 of that Regulation, the Union list will apply from the date of application of the delegated acts concerned, adopted pursuant to Article 11 of the same Regulation. The Union list may be amended in accordance with the requirements laid down in Article 16 of that Regulation.

(2) In its Opinion of 6 January 2006[7], the European Food Safety Authority (the Authority) concluded that the use of ferrous bisglycinate, as a source of iron in foods intended for the general population, food supplements, and foods for particular nutritional uses including foods intended for infants and young children does not present a safety concern.

(3) Ferrous bisglycinate was not included in the Annex to Regulation (EU) No 609/2013 for use, as a source of iron, in processed cereal-based food and baby food pending the review of the rules applicable to these products. As this review requires further on going scientific assessments that will not be concluded in the short term, it is not appropriate, in the light of good administrative practices, to further delay the update of the Union list as regards the inclusion of ferrous bisglycinate, as a source of iron in processed cereal-based food and baby food.

(4) Following an application, the Commission requested the Authority to provide an opinion on the safety and bioavailability of calcium phosphoryl oligosaccharides

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6 OJ L 181, 29.6.2013, p. 35.

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

(POs-Ca®), as a source of calcium added for nutritional purposes to food, food supplements and foods for special medical purposes. In its Opinion of 26 April[8], the Authority concluded that there is no safety concern for the use of this substance in the mentioned categories of food provided that certain conditions detailed in its opinion are respected. The Authority noted that this substance would be a major contributor to the overall average daily intake of calcium.

(5) The Annex to Regulation (EC) No 609/2013, should therefore be amended accordingly.

(6) The interested parties were consulted and the comments provided were taken into consideration.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 609/2013 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

[8] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2016, Scientific Opinions on Calcium phosphyoryl 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.