

COMMISSION DELEGATED REGULATION (EU) 2017/1091**of 10 April 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****(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 ⁽¹⁾, 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 ⁽²⁾, 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 (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 2016 ⁽³⁾, 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 (EU) No 609/2013, should therefore be amended accordingly.
- (6) The interested parties were consulted and the comments provided were taken into consideration,

⁽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), 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.

⁽³⁾ 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.

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, 10 April 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The Annex to Regulation (EU) No 609/2013 is amended as follows:

- (a) in substance 'Calcium', the following entry is inserted after the entry for 'calcium L-pidolate':

'calcium phosphoryl oligosaccharides			X'	
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- (b) in substance 'Iron', the entry 'ferrous bisglycinate' is replaced by the following:

'ferrous bisglycinate	X	X	X	X'
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