

Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 concerning the authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 601/2013

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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 (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.
- (2) Cobaltous acetate, basic cobaltous carbonate and cobaltous sulphate were authorised without a time limit by Directive 70/524/EEC. These products were subsequently entered in the Community Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of cobaltous acetate, basic cobaltous carbonate and cobaltous sulphate as feed additives for all animal species. Additionally, an application based on Article 10(2) was submitted for the re-evaluation of basic cobaltous carbonate in a film granulated form for all animal species. Thirdly, in accordance with Article 7 of that Regulation, an application was submitted for the authorisation of cobalt carbonate for ruminants, horses and rabbits. For all five compounds of cobalt it was requested that the additives to be classified in the additive category 'nutritional additives'. The three applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

Changes to legislation: Commission Implementing Regulation (EU) No 601/2013, Introductory Text is up to date with all changes known to be in force on or before 11 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 June 2012⁽³⁾⁽⁴⁾ and 22 May 2012⁽⁵⁾ that, under the proposed conditions of use, cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate do not have an adverse effect on animal health, consumer health or the environment, and that they are an effective sources of cobalt in the respective target species. The Authority also concluded that no safety concerns would arise for users provided that appropriate protective measures are taken to avoid inhalation. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.
- (6) Since safety reasons do not require the immediate application of the modifications for the already authorised cobalt compounds, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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- (1) OJ L 268, 18.10.2003, p. 29.
- (2) OJ L 270, 14.12.1970, p. 1.
- (3) EFSA Journal 2012; 10(7):2791.
- (4) EFSA Journal 2012; 10(7):2782.
- (5) EFSA Journal 2012; 10(6):2727.

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