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

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)

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.

(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:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

[*F1* *Article 1a*

Amendment to Commission Regulation (EC) No 1334/2003[6]

In the Annex to Regulation (EC) No 1334/2003, the entries 'cobaltous acetate tetrahydrate', 'basic cobaltous carbonate monohydrate' and 'cobaltous sulphate heptahydrate', related to the element E3 Cobalt-Co, are deleted.**]**

Textual Amendments

F1 Inserted by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014 amending Implementing Regulation (EU) No 601/2013 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).

[F2 Article 2

Transitional measures

The substances specified in the Annex which were authorised by Directive 70/524/EEC and feed containing them, which are produced and labelled before 4 September 2014 in accordance with the rules applicable before 15 July 2013 may continue to be placed on the market and used until the existing stocks are exhausted. As regards feed intended for pet animals, the time period for production and labelling referred to in the first sentence shall end on 4 March 2016.**]**

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014 amending Implementing Regulation (EU) No 601/2013 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).

Article 3

Entry into force

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 601/2013. (See end of Document for details)*

[F2ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Element (Co) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b301	—	Cobalt(II) acetate tetrahydrate	*Additives consisting of* Cobalt(II) acetate tetrahydrate, *active substance* Chemical formula: $Co(CH_3COO)_2 \times 4H_2O$ CAS number: 6147-53-1 *Characterisation of the active substance* Cobalt(II) acetate tetrahydrate, crystals, with a minimum content of 23 % cobalt Particles < 50 µm: below 1 %	*Additives with the exception of* ruminants — herbivores, lagomorphs, rodents, reptiles and zoo mammals	—	1 (total)	1. The additive shall be incorporated into compound feed in the form of a premixture. 2. Protective measures shall be taken according to national regulations implementing EU legislation on health and safety at work including Council	15 July 2023

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

b OJ L 183, 29.6.1989, p. 1.

c OJ L 393, 30.12.1989, p. 18.

d OJ L 348, 28.11.1992, p. 1.

e OJ L 131, 5.5.1998, p. 11.

f OJ L 399, 30.12.1989, p. 18.

g OJ L 158, 30.4.2004, p. 50.]

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 601/2013. (See end of Document for details)*

				Analytical methods[a]	For the identification of acetate in the additive: —	European Pharmacopoeia monograph 01/2008:20301.		Directives 89/391/EEC[b], 89/656/EEC[c], 92/85/EEC[d] and 98/24/EC[e]. Appropriate protective gloves, respiratory and eye protection according to Council Directive 89/686/EEC[f] shall be worn during handling.	
					For the crystallographic characterisation of additive: —	X-Ray diffraction.			
					For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: —	EN 15510 — inductively coupled plasma		3. Declarations to be made on the labelling of the additive and premixture: — Cobalt content — ‘It is recommended to limit	

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

b OJ L 183, 29.6.1989, p. 1.

c OJ L 393, 30.12.1989, p. 18.

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e OJ L 131, 5.5.1998, p. 11.

f OJ L 399, 30.12.1989, p. 18.

g OJ L 158, 30.4.2004, p. 50.**]**