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<sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- 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<sup>(2)</sup>.
- (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<sup>(3)(4)</sup> and 22 May 2012<sup>(5)</sup> 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 (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.

# [<sup>F1</sup>Article 1a

## Amendment to Commission Regulation (EC) No 1334/2003<sup>(6)</sup>

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).

# $\int^{F^2}Article 2$

## **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.

# [<sup>F2</sup>ANNEX

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**c** OJ L 393, 30.12.1989, p. 18.

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**b** OJ L 183, 29.6.1989, p. 1.

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**c** OJ L 393, 30.12.1989, p. 18.

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b	OJ L 183, 29.6.1989, p. 1.
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<b>Changes to legislation:</b> There are currently no known outstanding a	effects for the
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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.]

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

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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.

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e OJ L 131, 5.5.1998, p. 11.

**f** OJ L 399, 30.12.1989, p. 18.

		and feed materials — For determin of	EN 15510 – inductiv coupled plasma optical (atomic) emissior spectron (ICP- AES) or CEN/ TS 15621 – inductiv coupled plasma optical (atomic) emissior spectron (ICP- AES) after pressure digestion	ely n netry ely n netry	kg in complete feed. In this context, the risk for Cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account.'
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			size analysis		
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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.

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

			diffraction methods.		
3b305	Cobalt(II) sulphate heptahydrate	rtnhiinateswith positionfunctionfunctionfunctionfunctionfunctionfunctionsupplicithagomorphs,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,podeder,	— 1 (total)	1.	15 July 2023 additive shall be incorporated into compound feed in the form of a premixture. This compound feed shall be placed on the market in a non- powder form. Appropriate measures shall be
		identific of sulphate in the additive			taken to avoid the cobalt emission

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.

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	methods are available at the follo URLs/EURL_feed_additives/Pag		oi ine Keierence Laboratory:	nup://
OJ L 183, 29.6.1989, p. 1	1			
OJ L 393, 30.12.1989, p.	. 18.			
OJ L 348, 28,11,1992, p.	1.			

**d** OJ L 348, 28.11.1992, p. 1.

e OJ L 131, 5.5.1998, p. 11.

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**f** OJ L 399, 30.12.1989, p. 18.

1 1 1 1	I	coupled	I	EEC,
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		(atomic)		92/85/
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OJ L 183, 29.6.1989, p. 1.				

**c** OJ L 393, 30.12.1989, p. 18.

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**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.

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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.]

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b	OJ L 1	83, 29.6.198	9, 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 3	399, 30.12.19	89, p. 18.							
g	OJ L 1	58, 30.4.200	4, p. 50.]							

- (**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.
- (6) [<sup>F1</sup>OJ L 187, 26.7.2003, p. 11.]

#### **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).

## Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 601/2013.