►**B** **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)

(OJ L 172, 25.6.2013, p. 14)

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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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.

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(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 June 2012 ([1]) ([2]) and 22 May 2012 ([3]) 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.

([1]) EFSA Journal 2012; 10(7):2791.
([2]) EFSA Journal 2012; 10(7):2782.
([3]) EFSA Journal 2012; 10(6):2727.

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Article 1a

Amendment to Commission Regulation (EC) No 1334/2003 ([1])

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.

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.

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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.

([1]) OJ L 187, 26.7.2003, p. 11.

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ANNEX

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	*Additive composition* Cobalt(II) acetate tetrahydrate, as crystals/granules, with a minimum content of 23 % cobalt Particles < 50 μm: below 1 % *Characterisation of the active substance* Chemical formula: $Co(CH_3COO)_2 \times 4H_2O$ CAS number: 6147-53-1 *Analytical methods* ([1]) For the identification of acetate in the additive: — European Pharmacopoeia monograph 01/2008:20301. For the crystallographic characterisation of additive: — X-Ray diffraction. For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore 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 Directives 89/391/EEC ([2]), 89/656/EEC ([3]), 92/85/EEC ([4]) and 98/24/EC ([5]). Appropriate protective gloves, respiratory and eye protection according to Council Directive 89/686/EEC ([6]) shall be worn during handling. 3. Declarations to be made on the labelling of the additive and premixture: — Cobalt content — ‘It is recommended to limit the supplementation with Cobalt to 0,3 mg/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.’	15 July 2023

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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 %			
			— EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) or — CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion. For determination of particle size distribution: — ISO 13320:2009 — Particle size analysis — Laser diffraction methods.					4. Declarations to be made on the instructions of use of the compound feed: ‘Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.’	
3b302	—	Cobalt(II) carbonate	*Additive composition* Cobalt(II) carbonate, as powder, with a minimum content of 46 % cobalt Cobalt carbonate: minimum 75 % Cobalt hydroxide: 3 % - 15 % Water: maximum 6 % Particles < 11 μm: below 90 % *Characterisation of the active substances*	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	1. The 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. 2. Appropriate measures shall be taken to avoid the cobalt emission in the air and prevent the exposure by inhalation or by dermal route. If such measures are technically not feasible or not sufficient, protective measures shall be taken according to national	15 July 2023

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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 %			
			Chemical formula: $CoCO_3$ CAS number: 513-79-1 *Analytical methods* For the identification of carbonate in the additive: — European Pharmacopoeia monograph 01/2008:20301. 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 optical (atomic) emission spectrometry (ICP-AES) or — CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion. For determination of particle size distribution: — ISO 13320:2009 — Particle size analysis — Laser diffraction methods.					regulations implementing EU legislation on health and safety at work including Directives 89/391/EEC, 89/656/EEC, 92/85/EEC, 98/24/EC and 2004/37/EC of the European Parliament and of the Council. Appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC shall be worn during handling. 3. Declarations to be made on the labelling of the additive and premixture: — Cobalt content — 'It is recommended to limit the supplementation with Cobalt to 0,3 mg/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.' 4. Declarations to be made on the instructions of use of the compound feed: 'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'	

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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 %			
3b303	—	Cobalt(II) carbonate hydroxide (2:3) monohydrate	*Additive composition* Cobalt (II) carbonate hydroxide (2:3) monohydrate, as powder, with a minimum content of 50 % cobalt Particles < 50 μm: below 98 % *Characterisation of the active substance* Chemical formula: $2CoCO_3 \times 3Co(OH)_2 \times H_2O$ CAS number: 51839-24-8 *Analytical methods* (1) For the identification of carbonate in the additive: — European Pharmacopoeia monograph 01/2008:20301. 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 optical (atomic) emission spectrometry (ICP-AES) or	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	1. The 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. 2. Appropriate measures shall be taken to avoid the cobalt emission in the air and prevent the exposure by inhalation or by dermal route. If such measures are technically not feasible or not sufficient, protective measures shall be taken according to national regulations implementing EU legislation on health and safety at work including Directives 89/391/EEC, 89/656/EEC, 92/85/EEC, 98/24/EC and 2004/37/EC. Appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC shall be worn during handling. 3. Declarations to be made on the labelling of the additive and premixture: — Cobalt content — 'It is recommended to limit the supplementation with Cobalt to 0,3 mg/kg in complete feed. In this context, the risk for Cobalt	15 July 2023

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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 %			
			— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion. For determination of particle size distribution: — ISO 13320:2009 — Particle size analysis — Laser diffraction methods.					deficiency due to local conditions and the specific composition of the diet should be taken into account.' 4. Declarations to be made on the instructions of use of the compound feed: 'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'	
3b304	—	Coated granulated cobalt(II) carbonate	*Additive composition* Coated granulated preparation of cobalt(II) carbonate with a cobalt content of 1 % - 5 % Coating agents (2,3 % - 3,0 %) and dispersants (choice of poly-oxyethylene, sorbitan monolaurate, glycerol polyethyleneglycol ricinoleate, polyethyleneglycol 300, sorbitol, and maltodextrin) Particles < 50 μm: below 1 % *Characterisation of the active substance* Chemical formula: $CoCO_3$ CAS number: 513-79-1 *Analytical methods* ([1])	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	1. The additive shall be incorporated into 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 Directives 89/391/EEC, 89/656/EEC, 92/85/EEC and 98/24/EC. Appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC shall be worn during handling. 3. Declarations to be made on the labelling of the additive and premixture, if applicable: — Cobalt content	15 July 2023

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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 %			
			For the identification of carbonate in the additive: — European Pharmacopoeia monograph 01/2008:20301. 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 optical (atomic) emission spectrometry (ICP-AES) or — CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion. For determination of particle size distribution: — ISO 13320:2009 — Particle size analysis — Laser diffraction methods.					— ‘It is recommended to limit the supplementation with Cobalt to 0,3 mg/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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						Element (Co) in mg/kg of complete feed with a moisture content of 12 %			
3b305	—	Cobalt(II) sulphate heptahydrate	*Additive composition* Cobalt(II) sulphate heptahydrate, as powder, with a minimum content of 20 % cobalt Particles < 50 μm: below 95 % *Characterisation of the active substance* Chemical formula: $CoSO_4 \times 7H_2O$ CAS number: 10026-24-1 *Analytical methods* (1) For the identification of sulphate in the additive: — European Pharmacopoeia monograph 01/2008:20301. 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 optical (atomic) emission spectrometry (ICP-AES) or	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	1. The 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. 2. Appropriate measures shall be taken to avoid the cobalt emission in the air and prevent the exposure by inhalation or by dermal route. If such measures are technically not feasible or not sufficient, protective measures shall be taken according to national regulations implementing EU legislation on health and safety at work including Directives 89/391/EEC, 89/656/EEC, 92/85/EEC, 98/24/EC and 2004/37/EC. Appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC shall be worn during handling. 3. Declarations to be made on the labelling of the additive and premixture: — Cobalt content — 'It is recommended to limit the supplementation with Cobalt to 0,3 mg/kg in complete feed. In this context, the risk for Cobalt	15 July 2023

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						Element (Co) in mg/kg of complete feed with a moisture content of 12 %			
			— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion. For determination of particle size distribution: — ISO 13320:2009 — Particle size analysis — Laser diffraction methods.					deficiency due to local conditions and the specific composition of the diet should be taken into account.' 4. Declarations to be made on the instructions of use of the compound feed: 'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'	

([1]) 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
([2]) OJ L 183, 29.6.1989, p. 1.
([3]) OJ L 393, 30.12.1989, p. 18.
([4]) OJ L 348, 28.11.1992, p. 1.
([5]) OJ L 131, 5.5.1998, p. 11.
([6]) OJ L 399, 30.12.1989, p. 18.
([7]) OJ L 158, 30.4.2004, p. 50.