

## 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)

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:

- (1) Commission Implementing Regulation (EU) No 601/2013<sup>(2)</sup> authorised 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 belonging to the category 'nutritional additives' and to the functional group 'compounds of trace elements'.
- (2) In order to clarify the identification of the additive cobalt(II) carbonate, the chemical formula Cobalt hydroxide should be deleted from the active substances.
- (3) For better clarity and to avoid confusion with the identification numbers of selenium compounds authorised as feed additives, it is appropriate to technically modify the identification numbers for the cobalt compounds.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 June 2012<sup>(3)</sup>,<sup>(4)</sup> and 22 May 2012<sup>(5)</sup> that specific measures for the protection of the users should be foreseen. The respective requirement that compounds with a high dusting

potential must be placed on the market in a pelleted form could be expanded to other non-powder forms without compromising the risk for the users.

- (5) The applicant for coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate submitted data in order to substantiate that the substance coated is cobalt(II) carbonate and not cobalt(II) carbonate hydroxide (2:3) monohydrate. After verification in the application dossier which was the basis for the above mentioned opinion of the Authority<sup>(6)</sup>, it appears necessary to change the authorisation terms of this product accordingly.
- (6) As a result of the granting of new authorisations by Implementing Regulation (EU) No 601/2013, the provisions of Commission Regulation (EC) No 1334/2003<sup>(7)</sup> concerning cobaltous acetate tetrahydrate, basic cobaltous carbonate monohydrate and cobaltous sulphate heptahydrate are obsolete and should be deleted.
- (7) As a consequence of these modifications, the transitional period provided for in Implementing Regulation (EU) No 601/2013 should be extended in order to allow interested parties to prepare themselves to meet the requirements resulting from the amendments. As regards feed intended for pet animals, the market consists in a huge number of different products with a specific labelling system. It is therefore appropriate to prolong such a transitional period in order to allow a smooth transition for the feed business operators concerned.
- (8) Implementing Regulation (EU) No 601/2013 should be amended accordingly.
- (9) In addition, a transitional period for operators who applied the provisions of Implementing Regulation (EU) No 601/2013 should be established.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> 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 (OJ L 172, 25.6.2013, p. 14).

<sup>(3)</sup> EFSA Journal 2012; 10(7):2791.

<sup>(4)</sup> EFSA Journal 2012; 10(7):2782.

<sup>(5)</sup> EFSA Journal 2012; 10(6):2727.

<sup>(6)</sup> EFSA Journal 2012; 10(7):2782.

<sup>(7)</sup> Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11).

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendment to Implementing Regulation (EU)  
No 601/2013**

Implementing Regulation (EU) No 601/2013 shall be amended as follows:

1. The following Article 1a is added:

*'Article 1a*

**Amendment to Commission Regulation (EC)  
No 1334/2003 (\*)**

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.

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(\*) OJ L 187, 26.7.2003, p. 11.'

2. Article 2 is replaced by the following:

*'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.'

3. The Annex is replaced by the text set out in the Annex to this Regulation.

*Article 2*

**Transitional measures**

The substances specified in the Annex which were authorised by Implementing Regulation (EU) No 601/2013 and feed containing them, which are produced and labelled before 4 September 2014 in accordance with the rules applicable before 4 March 2014 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.

*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.

Done at Brussels, 11 February 2014.

*For the Commission*

*The President*

José Manuel BARROSO

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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 %			
<b>Category of nutritional additives. Functional group: compounds of trace elements</b>									
3b301	—	Cobalt(II) acetate tetrahydrate	<p><i>Additive composition</i></p> <p>Cobalt(II) acetate tetrahydrate, as crystals/granules, with a minimum content of 23 % cobalt</p> <p>Particles &lt; 50 µm: below 1 %</p> <p><i>Characterisation of the active substance</i></p> <p>Chemical formula: Co(CH<sub>3</sub>COO)<sub>2</sub> × 4H<sub>2</sub>O</p> <p>CAS number: 6147-53-1</p> <p><i>Analytical methods</i> <sup>(1)</sup></p> <p>For the identification of acetate in the additive:</p> <p>— European Pharmacopoeia monograph 01/2008:20301.</p> <p>For the crystallographic characterisation of additive:</p> <p>— X-Ray diffraction.</p> <p>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</p> <p>— EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES)</p> <p>or</p>	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	<ol style="list-style-type: none"> <li>The additive shall be incorporated into compound feed in the form of a premixture.</li> <li>Protective measures shall be taken according to national regulations implementing EU legislation on health and safety at work including Council Directives 89/391/EEC <sup>(2)</sup>, 89/656/EEC <sup>(3)</sup>, 92/85/EEC <sup>(4)</sup> and 98/24/EC <sup>(5)</sup>. Appropriate protective gloves, respiratory and eye protection according to Council Directive 89/686/EEC <sup>(6)</sup> shall be worn during handling.</li> <li>Declarations to be made on the labelling of the additive and premixture: <ul style="list-style-type: none"> <li>— Cobalt content</li> <li>— “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.”</li> </ul> </li> <li>Declarations to be made on the instructions of use of the compound feed: <p>‘Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.’</p> </li> </ol>	15 July 2023

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 %			
			<p>— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion.</p> <p>For determination of particle size distribution:</p> <p>— ISO 13320:2009 — Particle size analysis — Laser diffraction methods.</p>						
3b302	—	Cobalt(II) carbonate	<p><i>Additive composition</i></p> <p>Cobalt(II) carbonate, as powder, with a minimum content of 46 % cobalt  Cobalt carbonate: minimum 75 %  Cobalt hydroxide: 3 % - 15 %  Water: maximum 6 %  Particles &lt; 11 µm: below 90 %</p> <p><i>Characterisation of the active substances</i></p> <p>Chemical formula: <math>\text{CoCO}_3</math></p> <p>CAS number: 513-79-1</p> <p><i>Analytical methods</i> <sup>(1)</sup></p> <p>For the identification of carbonate in the additive:</p> <p>— European Pharmacopoeia monograph 01/2008:20301.</p> <p>For the crystallographic characterisation of additive:</p> <p>— X-Ray diffraction.</p>	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	<ol style="list-style-type: none"> <li>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.</li> <li>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 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.</li> <li>Declarations to be made on the labelling of the additive and premixture: <ul style="list-style-type: none"> <li>— Cobalt content</li> </ul> </li> </ol>	15 July 2023

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 %			
			<p>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</p> <p>— EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES)</p> <p>or</p> <p>— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion.</p> <p>For determination of particle size distribution:</p> <p>— ISO 13320:2009 — Particle size analysis — Laser diffraction methods.</p>					<p>— '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.'</p> <p>4. Declarations to be made on the instructions of use of the compound feed:</p> <p>'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'</p>	
3b303	—	Cobalt(II) carbonate hydroxide (2:3) monohydrate	<p><i>Additive composition</i></p> <p>Cobalt (II) carbonate hydroxide (2:3) monohydrate, as powder, with a minimum content of 50 % cobalt</p> <p>Particles &lt; 50 µm: below 98 %</p> <p><i>Characterisation of the active substance</i></p> <p>Chemical formula: 2CoCO<sub>3</sub> × 3Co(OH)<sub>2</sub> × H<sub>2</sub>O</p> <p>CAS number: 51839-24-8</p> <p><i>Analytical methods</i> <sup>(1)</sup></p> <p>For the identification of carbonate in the additive:</p> <p>— European Pharmacopoeia monograph 01/2008:20301.</p>	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	<p>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.</p> <p>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.</p> <p>3. Declarations to be made on the labelling of the additive and premixture:</p> <p>— Cobalt content</p>	15 July 2023

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 %			
			<p>For the crystallographic characterisation of additive:</p> <p>— X-Ray diffraction.</p> <p>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</p> <p>— EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES)</p> <p>or</p> <p>— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion.</p> <p>For determination of particle size distribution:</p> <p>— ISO 13320:2009 — Particle size analysis — Laser diffraction methods.</p>					<p>— '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.'</p> <p>4. Declarations to be made on the instructions of use of the compound feed:</p> <p>'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'</p>	
3b304	—	Coated granulated cobalt(II) carbonate	<p><i>Additive composition</i></p> <p>Coated granulated preparation of cobalt(II) carbonate with a cobalt content of 1 % - 5 %</p> <p>Coating agents (2,3 % - 3,0 %) and dispersants (choice of poly-oxy-ethylene, sorbitan monolaurate, glycerol polyethyleneglycol ricinoleate, polyethyleneglycol 300, sorbitol, and maltodextrin)</p> <p>Particles &lt; 50 µm: below 1 %</p> <p><i>Characterisation of the active substance</i></p> <p>Chemical formula: CoCO<sub>3</sub></p> <p>CAS number: 513-79-1</p>	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	<ol style="list-style-type: none"> <li>The additive shall be incorporated into feed in the form of a premixture.</li> <li>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.</li> <li>Declarations to be made on the labelling of the additive and premixture, if applicable: <ul style="list-style-type: none"> <li>— Cobalt content</li> </ul> </li> </ol>	15 July 2023

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 %			
			<p><i>Analytical methods</i> <sup>(1)</sup></p> <p>For the identification of carbonate in the additive:</p> <p>— European Pharmacopoeia monograph 01/2008:20301.</p> <p>For the crystallographic characterisation of additive:</p> <p>— X-Ray diffraction.</p> <p>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</p> <p>— EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES)</p> <p>or</p> <p>— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion.</p> <p>For determination of particle size distribution:</p> <p>— ISO 13320:2009 — Particle size analysis — Laser diffraction methods.</p>					<p>— '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.'</p>	
3b305	—	Cobalt(II) sulphate heptahydrate	<p><i>Additive composition</i></p> <p>Cobalt(II) sulphate heptahydrate, as powder, with a minimum content of 20 % cobalt</p> <p>Particles &lt; 50 µm: below 95 %</p> <p><i>Characterisation of the active substance</i></p> <p>Chemical formula: <math>\text{CoSO}_4 \times 7\text{H}_2\text{O}</math></p> <p>CAS number: 10026-24-1</p>	ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	—	—	1 (total)	<p>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.</p> <p>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</p>	15 July 2023

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 %			
			<p><i>Analytical methods</i> <sup>(1)</sup></p> <p>For the identification of sulphate in the additive:</p> <p>— European Pharmacopoeia monograph 01/2008:20301.</p> <p>For the crystallographic characterisation of additive:</p> <p>— X-Ray diffraction.</p> <p>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</p> <p>— EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES)</p> <p>or</p> <p>— CEN/TS 15621 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion.</p> <p>For determination of particle size distribution:</p> <p>— ISO 13320:2009 — Particle size analysis — Laser diffraction methods.</p>					<p>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.</p> <p>3. Declarations to be made on the labelling of the additive and premixture:</p> <p>— Cobalt content</p> <p>— '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.'</p> <p>4. Declarations to be made on the instructions of use of the compound feed:</p> <p>'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'</p>	

<sup>(1)</sup> 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](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)

<sup>(2)</sup> OJ L 183, 29.6.1989, p. 1.

<sup>(3)</sup> OJ L 393, 30.12.1989, p. 18.

<sup>(4)</sup> OJ L 348, 28.11.1992, p. 1.

<sup>(5)</sup> OJ L 131, 5.5.1998, p. 11.

<sup>(6)</sup> OJ L 399, 30.12.1989, p. 18.

<sup>(7)</sup> OJ L 158, 30.4.2004, p. 50.'