

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1455**of 13 July 2023****concerning the urgent provisional authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate as feed additives for ruminants with a functional rumen, equidae and lagomorphs****(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 15 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. In particular, Article 15 of that Regulation provides that the Commission may provisionally authorise the use of additives in specific cases where urgent authorisation is needed to ensure the protection of animal welfare.
- (2) Commission Implementing Regulation (EU) No 601/2013 ⁽²⁾ authorised for a period of 10 years cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate, heptahydrate and coated granulated cobalt(II) carbonate as feed additives belonging to the category 'nutritional additives' and to the functional group 'compounds of trace elements'. Those additives were authorised for use in ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.
- (3) No application was submitted within the time limit indicated in Article 14(1) of Regulation (EC) No 1831/2003 for the renewal of the authorisation of the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate ⁽³⁾, expiring on 15 July 2023. For those additives, an application for a new authorisation was submitted on 20 October 2022 in accordance with Article 7 of Regulation (EC) No 1831/2003, for use for the same animal species that the previous authorisation concerned and requesting them to be classified in the additive category 'nutritional additives' and in the functional group 'compounds of trace elements'.
- (4) Taking into account the time period needed for the processing of the application for authorisation submitted for the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate, no new authorisation of those additives can be granted by 15 July 2023.
- (5) As a result, a request was submitted by a company to the Commission on 30 May 2023, to grant, in accordance with Article 15 of Regulation (EC) No 1831/2003, a provisional urgent authorisation of the use of the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate, intended for ruminants, horses and rabbits.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ 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).

⁽³⁾ An application was submitted for the renewal of the authorisation of coated granulated cobalt(II) carbonate as a feed additive in accordance with Article 14(1) of Regulation (EC) No 1831/2003. That additive is not covered by this Regulation.

- (6) In its opinion of 12 November 2009 ⁽⁴⁾, the European Food Safety Authority ('the Authority') concluded that due to the high ruminal degradation rate of oral vitamin B₁₂, an optimal micronutrient supply of ruminants should include cobalt. The Authority extended that conclusion to horses and rabbits, for which it considered that cobalt supplementation to their diets should also be maintained. In its opinions of 22 May 2012 ⁽⁵⁾ and 12 June 2012 ⁽⁶⁾, the Authority confirmed that the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate are efficacious sources of cobalt as an essential trace element, which is in turn used for the production of vitamin B₁₂ by microbial fermentation in the rumen.
- (7) As mentioned in the Authority's opinion of 12 November 2009, cobalt deficiency in animals results in general in loss of appetite, reduced growth rate, loss of body weight, anaemia, disturbances of lipid metabolism, reduced folate level, accumulation of iron and nickel in liver, compromised neutrophil function and reduced resistance to parasitic infections, which is particularly the case as regards ruminants.
- (8) It appears therefore that such deficiency is likely to cause severe adverse effects on the welfare of animals for which cobalt is essential to synthesise vitamin B₁₂, including a weakening of the immune system, an increase in the frequency of intestinal disorders and ketosis, an impaired reproductive function, an increased risk for ovines of contracting the Ovine White Liver Disease and even possibly an increase in morbidity or mortality ⁽⁷⁾.
- (9) In order to avoid critical deficiencies, animals grazing on soils low in cobalt, or fed with hay or plants produced in those soils, but also certain animal categories with specific needs, such as animals fed with automatic concentrate dispensers with metering pumps or some animals with metabolic disorders, rely on complementary feed in the form of bolus or liquid for their supply in essential nutrients, including cobalt. The alternative for grassland animals to use buckets or mineral licks to administer feed is generally not considered as optimal in all circumstances to guarantee a sufficient, effective and safe supply of cobalt, due to the voluntary and competitive consumption thereof by animals and the derived less controlled and targeted supplementation, the impact of climatic conditions on feed's quality and the additional requirements in terms of handling.
- (10) The additive coated granulated cobalt(II) carbonate, for the use of which an application for renewal has been submitted in accordance with Article 14(1) of Regulation (EC) No 1831/2003 and which is currently authorised as a feed additive in accordance with Regulation (EC) No 1831/2003, cannot be used in the formulation of feed administered in liquid complementary feed, nor as bolus. This is because of the technical specifications of that additive, which contains insoluble particles affecting the homogeneity of the liquid feed, has a very low cobalt concentration and is not very compressible, preventing the manufacture of suitable high-density boluses. Liquid feed should contain cobalt in soluble form, such as the additives cobalt(II) acetate tetrahydrate and cobalt(II) sulphate, heptahydrate, while the manufacturing of suitable boluses providing the animals with the required safe amount of cobalt would include the additives cobalt(II) carbonate and cobalt(II) carbonate hydroxide (2:3) monohydrate. No other cobalt compound is currently authorised as a feed additive pursuant to Regulation (EC) No 1831/2003.
- (11) Commission Regulation (EU) 2020/354 ⁽⁸⁾ establishes as particular nutritional purpose the long-term supply of grazing animals with trace elements and/or vitamins for feed intended for ruminants with a functional rumen, which is allowed to be administered in the form of bolus. A cessation of the use of cobalt compounds as an additive in feed, in particular dietetic feed in the form of bolus for grazing animals, would prevent operators from meeting

⁽⁴⁾ EFSA Journal 2009;7(12):1383.

⁽⁵⁾ EFSA Journal 2012;10(6):2727.

⁽⁶⁾ EFSA Journal 2012;10(7):2791.

⁽⁷⁾ A review of the role of cobalt in animal metabolism, in particular of ruminants, and of the effects of cobalt deficiency, is available in: 'Relationship between Vitamin B12 and Cobalt Metabolism in Domestic Ruminant: An Update', by Jose-Ramiro González-Montaña et al. Animals 2020, 10, 1855; doi:10.3390/ani10101855.

⁽⁸⁾ Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC (OJ L 67, 5.3.2020, p. 1).

that particular nutritional purpose with regard to the specific nutritional needs of ruminants whose process of assimilation, absorption or metabolism can be impaired by a lack of cobalt in their diet. Such lack of feed appropriate to the conditions of grazing ruminants would therefore be detrimental to the welfare of those animals.

- (12) The actual impact of the non-availability of the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate can be measured taking into consideration the extent of use of those additives across the Union, although some Member States are more affected by a cobalt deficiency due to the nature of soils and pastures. For instance, in Ireland, 62 % of all complementary feed manufactured for ruminants and equines contains one of those four additives and more than 11,7 million animals could potentially be negatively affected by a lack of access to those products. In France, 11,5 million ruminants are supplemented with one of those four additives in the form of bolus or liquid feed and would be affected in terms of animal welfare in the absence of use of those products. In general, it appears from data received from national competent authorities and operators that the additives concerned are widely used for ruminants, mostly in feed in the form of bolus or liquid, but also for horses and rabbits. It was estimated that, at the end of 2021, there were 76 million head of bovine animals and 71 million head of sheep and goats on Union farms ⁽⁹⁾. Statistical data on rabbit farming ⁽¹⁰⁾ from 2016 show that around 180 million farmed rabbits were reared for meat consumption in the Union.
- (13) Based on the Authority's opinions of 12 November 2009, 22 May 2012 and 12 June 2012, and data on the actual use of the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate in the Union, it derives that the animal species or categories whose welfare would be significantly impaired by the cessation of the use of cobalt in their nutrition are ruminants, horses and rabbits.
- (14) In order to avoid negative effects on the welfare of ruminants, horses and rabbits deriving from an interruption of the authorisation of the use of the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate, as from 15 July 2023, and in the absence of currently available alternative, their use should be urgently provisionally authorised until a decision on the application for their authorisation submitted in accordance with Article 7 of Regulation (EC) No 1831/2003 is taken. The provisional authorisation should be granted for a maximum period of five years, according to Article 15 of Regulation (EC) No 1831/2003.
- (15) In order to ensure that only safe and efficacious additives are used in accordance with the objectives pursued by Regulation (EC) No 1831/2003, the terms of the provisional authorisation should reflect the terms of authorisation provided for by Implementing Regulation (EU) No 601/2013 for the four additives concerned as regards the use intended for ruminants, equidae and lagomorphs.
- (16) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached for those additives in the earlier assessment carried out regarding the method of analysis in the context of the authorisation granted by Implementing Regulation (EU) No 601/2013 are valid and applicable to the provisional authorisation.
- (17) Due to the expiry of the authorisation of use of the additives cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate on 15 July 2023, and in order to ensure a high level of protection of the welfare of the animals concerned by the provisional authorisation, this Regulation should enter into force as a matter of urgency.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁹⁾ Key figures on the European food chain – 2022 edition, Eurostat.

⁽¹⁰⁾ European Commission, Directorate-General for Health and Food Safety, *Commercial rabbit farming in the European Union – Overview report*, Publications Office, 2018, <https://data.europa.eu/doi/10.2772/62174>

HAS ADOPTED THIS REGULATION:

Article 1

Provisional authorisation

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

Article 2

Entry into force

This Regulation shall enter into force on the 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, 13 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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	<i>Additive composition</i> Cobalt(II) acetate tetrahydrate, as crystals/granules, with a minimum content of 23% cobalt Particles < 50 µm: below 1 % <i>Characterisation of the active substance</i> Chemical formula: $\text{Co}(\text{CH}_3\text{COO})_2 \times 4\text{H}_2\text{O}$ CAS number: 6147-53-1 <i>Analytical methods ⁽¹⁾</i> <i>For the identification of acetate in the additive:</i> — European Pharmacopoeia monograph 01/2008:20301. <i>For the crystallographic characterisation of the additive:</i> — X-Ray diffraction. <i>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</i> — EN 15510 - inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) or	Ruminants with a functional rumen, equidae, lagomorphs	-	-	1 (total)	- The additive shall be incorporated into compound feed in the form of a premixture. - 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.' - For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	As soon as a decision on the authorisation of the additive has been taken under Article 9 of Regulation (EC) No 1831/2003 and at the latest on 14 July 2028.
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		— CEN/TS 15621 - inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion. <i>For the determination of particle size distribution:</i> — ISO 13320 - Particle size analysis - Laser diffraction methods.					4. Declaration to be made in 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	<i>Additive composition</i> Cobalt(II) carbonate, as powder, with a content of 45% - 48% cobalt Cobalt carbonate: minimum 75% Cobalt hydroxide: 3% - 15% Water: maximum 6% Particles < 11 µm: below 90 % <i>Characterisation of the active substance</i> Chemical formula: CoCO_3 CAS number: 513-79-1 <i>Analytical methods (*)</i> <i>For the identification of carbonate in the additive:</i>	Ruminants with a functional rumen, equidae, lagomorphs	-	-	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. 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.'	As soon as a decision on the authorisation of the additive has been taken under Article 9 of Regulation (EC) No 1831/2003 and at the latest on 14 July 2028.

		— European Pharmacopoeia monograph 01/2008:20301. <i>For the crystallographic characterisation of the additive:</i> — X-Ray diffraction. <i>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</i> — 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. <i>For the determination of particle size distribution:</i> — ISO 13320 - Particle size analysis - Laser diffraction methods.					3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment. 4. Declaration to be made in the instructions of use of the compound feed: 'Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken.'	
3b303	Cobalt(II) carbonate hydroxide (2:3) monohydrate	<i>Additive composition</i> Cobalt(II) carbonate hydroxide (2:3) monohydrate, as powder, with a minimum content of 50% cobalt Particles < 50 µm: below 98 %	Ruminants with a functional rumen, equidae, lagomorphs	-	-	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.	As soon as a decision on the authorisation of the additive has been taken under Article 9 of Regulation (EC) No 1831/2003 and at the latest on 14 July 2028.

		<i>Characterisation of the active substance</i> Chemical formula: $2\text{CoCO}_3 \times 3\text{Co(OH)}_2 \times \text{H}_2\text{O}$ CAS number: 51839-24-8 <i>Analytical methods (1)</i> <i>For the identification of carbonate in the additive:</i> — European Pharmacopoeia monograph 01/2008:20301. <i>For the crystallographic characterisation of the additive:</i> — X-Ray diffraction. <i>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</i> — 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. <i>For the determination of particle size distribution:</i> — ISO 13320 - Particle size analysis - Laser diffraction methods.					2. 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.' 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment. 4. Declaration to be made in 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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3b305	Cobalt(II) sulphate, heptahydrate	<i>Additive composition</i> Cobalt(II) sulphate, heptahydrate, as powder, with a minimum content of 20% cobalt Particles < 50 µm: below 95 % <i>Characterisation of the active substance</i> Chemical formula: $\text{CoSO}_4 \times 7\text{H}_2\text{O}$ CAS number: 10026-24-1 <i>Analytical methods ⁽¹⁾</i> <i>For the identification of sulphate in the additive:</i> — European Pharmacopoeia monograph 01/2008:20301. <i>For the crystallographic characterisation of the additive:</i> — X-Ray diffraction. <i>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</i> — 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.	Ruminants with a functional rumen, equidae, lagomorphs	-	-	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. 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.' 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	As soon as a decision on the authorisation of the additive has been taken under Article 9 of Regulation (EC) No 1831/2003 and at the latest on 14 July 2028.
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		<i>For the determination of particle size distribution:</i> — ISO 13320 - Particle size analysis - Laser diffraction methods.					4. Declaration to be made in 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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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en