SCHEDULE 2

Regulation 3

Form of provisional authorisation of cobalt(II) carbonate (identification number 3b302) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

The substance cobalt(II) carbonate, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is provisionally authorised as an additive in animal nutrition in accordance with the specifications in the following table.

Additive	Cobalt(II) carbonate
Identification number of the additive	3b302
Authorisation holder[(1)]	
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Cobalt(II) carbonate Powder containing 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 substance(s)	Chemical formula: $CoCO_3$ CAS number: 513-79-1[(2)]
Analytical methods[(3)]	For the identification of carbonate in the additive: • European Pharmacopoeia monograph 20301[(4)]
	For the crystallographic characterisation of the additive: • X-Ray diffraction
	For the determination of total cobalt in the additive, premixtures, feed materials and compound feed: • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510: 2017[(5)]; or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017[(6)]
	For the determination of particle size distribution: • Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020[(7)]
Species or category of animal	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

Additive		Cobalt(II) carbonate
Maximum age		Not applicable
Element (Co) in mg/kg of complete feed with a moisture content of 12%	*Minimum content*	No minimum
	Maximum content	1 (total)
Other provisions		1) The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powdered form 2) The following must be stated on the labelling of the additive and premixture: • The element (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) The following must be stated in the instructions for use of the compound feed: • "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken"
Start of provisional authorisation period		15 July 2023
End of provisional authorisation period		14 July 2028

(1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.

(2) This is a reference to the CAS Registry Number® assigned to this substance by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry.

(3) Details of the analytical methods are set out in the document referenced "JRC.D.5/FSQ/CvH/PRO/ag/Ares(2012)214390" and last updated on 6th June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(4) *"Monograph 20301: 2.3.1. Identification reactions of ions and functional groups".* European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online https://pheur.edqm.eu/home.

(5) BS EN 15510:2017 "*Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES*". Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution https://knowledge.bsigroup.com.

(6) BS EN 15621:2017 *"Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES".* Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution https://knowledge.bsigroup.com.

(7) BS ISO 13320:2020 "*Particle size analysis. Laser diffraction methods".* Published by the British Standards Institution on 31st July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.