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)

COMMISSION IMPLEMENTING REGULATION (EU) No 131/2014

of 11 February 2014

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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) Commission Implementing Regulation (EU) No 601/2013[(2)] 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[(3)],[(4)] and 22 May 2012[(5)] 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[6], 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[7] 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,

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[8]

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.

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 131/2014. (See end of Document for details)*

ANNEX

‘ANNEXDetails 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.aspxOJ L 183, 29.6.1989, p. 1.OJ L 393, 30.12.1989, p. 18.OJ L 348, 28.11.1992, p. 1.OJ L 131, 5.5.1998, p. 11.OJ L 399, 30.12.1989, p. 18.OJ L 158, 30.4.2004, p. 50.’Identification number of the additiveName of the holder of authorisationAdditiveComposition, chemical formula, description, analytical methodSpecies or category of animalMaximum ageMinimum contentMaximum contentOther provisionsEnd of period of authorisationElement (Co) in mg/kg of complete feed with a moisture content of 12 %Category of nutritional additives. Functional group: compounds of trace elements3b301—Cobalt(II) acetate tetrahydrateAdditive compositionCobalt(II) acetate tetrahydrate, as crystals/granules, with a minimum content of 23 % cobaltParticles < 50 μm: below 1 %Characterisation of the active substanceChemical formula: Co(CH3COO)2 × 4H2OCAS number: 6147-53-1Analytical methodsFor 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:EN 15510 — inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES)orCEN/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.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[b], 89/656/EEC[c], 92/85/EEC[d] and 98/24/EC[e]. Appropriate protective gloves, respiratory and eye protection according to Council Directive 89/686/EEC[f] shall be worn during handling.

3.Declarations to be made on the labelling of the additive and premixture:

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.’

15 July 20233b302—Cobalt(II) carbonateAdditive compositionCobalt(II) carbonate, as powder, with a minimum content of 46 % cobaltCobalt carbonate: minimum 75 %Cobalt hydroxide: 3 % - 15 %Water: maximum 6 %Particles < 11 μm: below 90 %Characterisation of the active substancesChemical formula: CoCO3CAS number: 513-79-1Analytical methodsFor 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)orCEN/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.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 of the European Parliament and of the