Commission Implementing Regulation (EU) 2018/1039 of 23 July 2018 concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006 and (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1039

of 23 July 2018

concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006 and (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261

(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) The copper compounds cupric acetate, monohydrate, basic cupric carbonate, monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, cupric chelate of amino acids, hydrate and cupric chelate of glycine hydrate were authorised without a time limit as feed additives for all animal species by Commission Regulation (EC) No 1334/2003[(3)] and Commission Regulation (EC) No 479/2006[(4)] in accordance with Directive 70/524/EEC. Those substances were subsequently entered in the 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 thereof, applications were submitted for the re-evaluation of cupric acetate, monohydrate, basic cupric carbonate, monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, cupric chelate of amino acids, hydrate and cupric chelate of glycine hydrate as feed additives for all animal species. The applicants requested that those additives be classified in the additive category 'nutritional additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) Due to scientific considerations, the European Food Safety Authority ('the Authority') recommended in its opinions of 14 November 2012[(5)], 31 January 2013[(6)] and 11 March 2015[(7)] to replace 'Cupric' by 'Copper(II)' in order to avoid potential misunderstandings. The Authority also recommended splitting Copper(II) chelate of amino acids into the following two groups, in view of its chemical characteristics: Copper(II) chelate of amino acids hydrate and Copper(II) chelate of protein hydrolysates.

(5) The Authority concluded that, under the proposed conditions of use, Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) ('substances concerned') do not have an adverse effect on animal health, consumer safety and the environment. Considering the capacities to be respiratory, eye and skin irritants, appropriate protective measures should be taken with respect to the handling of the additives concerned and premixtures containing them, in order to avoid that safety concerns for the users would arise.

(6) With respect to the nickel content of the additives, in particular in Copper(II) sulphate pentahydrate, certain batches of the additive might qualify for requirements set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(8)]. The feed business operator placing on the market such additives should comply with the relevant requirements. The Authority further concluded that the 'substances concerned' are efficacious in meeting animal copper requirements. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of the 'substances concerned' shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. However, the authority has concerns with respect to the strict adherence to the maximum quantity of copper administered to the animal if copper is added to water for drinking. Accordingly, the use of the substances concerned should be authorised as specified in the Annex to this Regulation and their use via water for drinking should be prohibited.

(8) With respect to the potential impacts on the environment, the Authority was requested to deliver a scientific opinion for a revision of the currently authorised maximum

copper content in complete feed. The Authority recommended in its opinion of 13 July 2016[9] to amend the authorised maximum copper contents in complete feed for different target species. These new levels should be adopted. However, for piglets the drastic recommended decrease to 25 mg/kg directly after weaning should not be done in one step, in order not to put at risk meeting the physiological needs of animals, particularly in that sensitive period, and to avoid any other negative impacts on the health of piglets. With the objective of a further reduction when the maximum contents are next reviewed to meet the maximum of 25 mg/kg for piglets directly after weaning, feed business operators and research institutes should be encouraged to collect new scientific data about the impacts of the levels recommended by the Authority on the health and welfare status of piglets and to promptly explore the use and effectiveness of alternatives to supplementation with copper as mentioned by the Authority.

(9) As a result of the granting of new authorisations for cupric acetate, monohydrate, basic cupric carbonate, monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, cupric chelate of amino acids, hydrate and cupric chelate of glycine hydrate, the complete entries for these substances in Regulations (EC) No 1334/2003 and (EC) No 479/2006 should be deleted. The authorisation for copperlysine sulphate expired on 31 March 2004. For reasons of legal certainty, it is appropriate to delete the entry concerning that substance from Regulation (EC) No 1334/2003.

(10) Commission Regulation (EU) No 349/2010[10] and Commission Implementing Regulations (EU) No 269/2012[11], (EU) No 1230/2014[12] and (EU) 2016/2261[13] authorised several copper compounds as nutritional feed additives. In order to take into account the conclusions of the Authority in its opinion of 13 July 2016, which were also the scientific basis for the provisions concerning the total copper content in compound feed for the additives authorised by this Regulation and which are mainly referring to the environmental impact of feed supplementation with copper, it is appropriate to align the maximum contents of copper in Regulation (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261 with the provisions of this Regulation as regards the copper content in compound feed. Regulation (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261 should therefore be amended accordingly.

(11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for cupric acetate, monohydrate, basic cupric carbonate, monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, cupric chelate of amino acids, hydrate and cupric chelate of glycine hydrate and the copper compounds authorised by Regulation (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1039. (See end of Document for details)

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 feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Special conditions of use

The authorised substances specified in the Annex as additives belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’ shall not be used in water for drinking.

Article 3

Amendment to Regulation (EC) No 1334/2003

In the Annex to Regulation (EC) No 1334/2003, the following additives are deleted from entry E4 for the element Copper-Cu: ‘cupric acetate, monohydrate, basic cupric carbonate, monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, copperlysine sulphate and cupric chelate of amino acids, hydrate’.

Article 4

Amendment to Regulation (EC) No 479/2006

In the Annex to Regulation (EC) No 479/2006, the entry E4 for the additive ‘Cupric chelate of glycine hydrate’ is deleted.

Article 5

Amendment to Regulation (EU) No 349/2010

In the Annex to Regulation (EU) No 349/2010, in the line 3b4.10 the text of the eighth column is replaced by the following:

Bovines:

— Bovines before the start of rumination: 15 (total);

— Other bovines: 30 (total).

Ovines: 15 (total).

Caprines: 35 (total)

Piglets:

— suckling and weaned up to 4 weeks after weaning: 150 (total);

— from 5-th week after weaning up to 8 weeks after weaning: 100 (total).

Crustaceans: 50 (total).

Other animals: 25 (total).

Article 6

Amendment to Implementing Regulation (EU) No 269/2012

In the Annex to Implementing Regulation (EU) No 269/2012, in the line 3b409 the text of the eighth column is replaced by the following:

Bovines:

— Bovines before the start of rumination: 15 (total);

— Other bovines: 30 (total).

Ovines: 15 (total).

Caprines: 35 (total)

Piglets:

— suckling and weaned up to 4 weeks after weaning: 150 (total);

— from 5-th week after weaning up to 8 weeks after weaning: 100 (total).

Crustaceans: 50 (total).

Other animals: 25 (total).

Article 7

Amendment to Implementing Regulation (EU) No 1230/2014

In the Annex to Implementing Regulation (EU) No 1230/2014, in the line 3b411 the text of the eighth column is replaced by the following:

Bovines:

— Bovines before the start of rumination: 15 (total);

— Other bovines: 30 (total).

Ovines: 15 (total).

Caprines: 35 (total)

Piglets:

— suckling and weaned up to 4 weeks after weaning: 150 (total);

— from 5-th week after weaning up to 8 weeks after weaning: 100 (total).

Crustaceans: 50 (total).

Other animals: 25 (total.