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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) 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).
([4]) Commission Regulation (EC) No 479/2006 of 23 March 2006 as regards the authorisation of certain additives belonging to the group compounds of trace elements (OJ L 86, 24.3.2006, p. 4).
([5]) *EFSA Journal* 2012;10(12):2969.
([6]) *EFSA Journal* 2013;11(2):3107.
([7]) *EFSA Journal* 2015;13(4):4057.

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 ([1]). 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 ([2]) 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 ([3]) and Commission Implementing Regulations (EU) No 269/2012 ([4]), (EU) No 1230/2014 ([5]) and (EU) 2016/2261 ([6]) 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

([1]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([2]) *EFSA Journal* 2016;14(8):4563.

([3]) Commission Regulation (EU) No 349/2010 of 23 April 2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species (OJ L 104, 24.4.2010, p. 31).

([4]) Commission Implementing Regulation (EU) No 269/2012 of 26 March 2012 concerning the authorisation of dicopper chloride trihydroxide as feed additive for all animal species (OJ L 89, 27.3.2012, p. 3).

([5]) Commission Implementing Regulation (EU) No 1230/2014 of 17 November 2014 concerning the authorisation of copper bilysinate as a feed additive for all animal species (OJ L 331, 18.11.2014, p. 18).

([6]) Commission Implementing Regulation (EU) 2016/2261 of 15 December 2016 concerning the authorisation of copper(I) oxide as a feed additive for all animal species (OJ L 342, 16.12.2016, p. 18).

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:

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'.

Article 8

Amendment to Implementing Regulation (EU) 2016/2261

In the Annex to Implementing Regulation (EU) 2016/2261, in the line 3b412 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 9

Transitional measures

1. The substances '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 authorised by Regulation (EC) No 1334/2003 and Regulation (EC) No 479/2006 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, and premixtures containing those substances, which are produced and labelled before 13 February 2019 in accordance with the rules applicable before 13 August 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 13 August 2019 in accordance with the rules applicable before 13 August 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 13 August 2020 in accordance with the rules applicable before 13 August 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 10

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, 23 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b401	—	Copper(II) diacetate monohydrate	*Additive composition* Copper(II) diacetate monohydrate as a powder with a minimum content of 31 % copper *Characterisation of the active substance* Chemical formula: $Cu(CH_3COO)_2 \cdot H_2O$ CAS Number: 6046-93-1 *Analytical methods* (1) For the identification of Copper(II) diacetate monohydrate in the feed additive: — European Pharmacopoeia Monographs 2146 and 20301 For the crystallographic characterisation of the feed additive: — X-Ray diffraction For the determination of total Cu content in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)	All animal species	—	—	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).	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			Determination of total Cu content in feed materials and compound feed: — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 [2], Annex IV-C) or — inductively coupled plasma atomic emission, ICP-AES (EN 15510 or CEN/TS 15621)					3. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.' — For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b402	—	Copper(II) carbonate dihydroxy monohydrate	*Additive composition* Copper(II) carbonate dihydroxy monohydrate as a powder with a minimum content of 52 % copper *Characterisation of the active substance* Chemical formula: $CuCO_3 \cdot Cu(OH)_2 \cdot H_2O$ CAS Number: 100742-53-8	All animal species	—	—	Bovines: — Bovines before the start of rumination: 15 (total); — Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total)	1. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			Analytical methods [1] For the identification of carbonate in the feed additive: — European Pharmacopoeia Monograph 20301 For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)				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).	2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 3. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b403	—	Copper(II) chloride dihydrate	*Additive composition* Copper(II) chloride dihydrate as a powder with a minimum content of 36 % copper *Characterisation of the active substance* Chemical formula: $CuCl_2 \cdot 2H_2O$ CAS Number: 10125-13-0 *Analytical methods* (1) For the identification of chloride in the feed additive: — European Pharmacopoeia Monograph 20301 For the crystallographic characterisation of the feed additive: — X-Ray diffraction	All animal species	—	—	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).	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)					3. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.' — For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b404	—	Copper(II) oxide	*Additive composition* Copper(II) oxide as a powder with a minimum content of 77 % copper *Characterisation of the active substance* Chemical formula: CuO CAS Number: 1317-38-0	All animal species	—	—	Bovines: — Bovines before the start of rumination: 15 (total); — Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total)	1. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			Analytical methods (1) For the crystallographic characterisation of the feed additive: — X-Ray diffraction For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)				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).	2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 3. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b405	—	Copper(II) sulphate pentahydrate	*Additive composition* Copper(II) sulphate pentahydrate as a powder with a minimum content of 24 % copper *Characterisation of the active substance* Chemical formula: $CuSO_4 \cdot 5H_2O$ CAS Number: 7758-99-8 *Analytical methods* (1) For the identification of Copper(II) sulphate pentahydrate in the feed additive: — European Pharmacopoeia Monographs 0894 and 20301 For the crystallographic characterisation of the feed additive: — X-Ray diffraction	All animal species	—	—	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).	1. Copper(II) sulphate pentahydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)					3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 4. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b406	—	Copper(II) chelate of amino acids hydrate	*Additive composition* Copper(II) amino acid complex where the copper and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 10 % copper *Characterisation of the active substance* Chemical formula: $Cu(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate. Maximum of 10 % of the molecules exceeding 1 500 Da	All animal species		—	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).	1. Copper(II) chelate of amino acids hydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			Analytical methods (1) For the quantification of the amino acid content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III-F) For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)					3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 4. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b407	—	Copper(II) chelate of protein hydrolysates	*Additive composition* Copper(II) chelate of protein hydrolysates as a powder with a minimum content of 10 % copper and a minimum of 50 % copper chelated *Characterisation of the active substance* Chemical formula: $Cu(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate *Analytical methods* (1) For the quantification of protein hydrolysates content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III-F)	All animal species	—	—	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).	1. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			For the qualitative verification of the chelation of the copper in the feed additive: — Fourier Transformed Infrared (FTIR) spectroscopy followed by multivariate regression methods For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)					2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 3. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b413	—	Copper(II) chelate of glycine hydrate (solid)	*Additive composition* Copper(II) chelate of glycine, hydrate, as a powder with a minimum content of 15 % copper and a maximum of 13 % moisture *Characterisation of the active substance* Chemical formula: $Cu(x)_{1-3} \cdot nH_2O$, x = anion of glycine *Analytical methods* (1) For the quantification of the glycine content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III-F)	All animal species	—	—	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).	1. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)					2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 3. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	
3b414	—	Copper(II) chelate of glycine hydrate (liquid)	*Additive composition* Copper(II) chelate of glycine, hydrate, as a liquid with a minimum content of 6 % copper *Characterisation of the active substance* Chemical formula: $Cu(x)_{1-3} \cdot nH_2O$, x = anion of glycine *Analytical methods* [1] For the quantification of the glycine content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III-F)				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).	1. Copper(II) chelate of glycine hydrate (liquid) may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	13 August 2028

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			For the determination of total Cu in the feed additive and premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621) For the determination of total Cu in feed materials and compound feed: — atomic absorption spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C) or — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or CEN/TS 15621)					3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 4. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'	

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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
								— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
(2) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).