COMMISSION IMPLEMENTING REGULATION (EU) 2016/1095

of 6 July 2016

concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006, (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013

(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 zinc compounds Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate were authorised without a time limit by Commission Regulations (EC) No 1334/2003 ([3]) and (EC) No 479/2006 ([4]) in accordance with Directive 70/524/EEC. These products 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 Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an application was submitted for Zinc chloride anhydrous as feed additive for all animal species. The applicants requested that those additives be classified in the additive category 'nutritional additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 1 February 2012 ([5]), 8 March 2012 ([6]), 23 May 2012 ([7]), 15 November 2012 ([8]), 12 September 2013 ([9]) and 12 March 2015 ([10]) that, under the proposed conditions of use, Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine

([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(2):2572.
([6]) EFSA Journal 2012;10(3):2621.
([7]) EFSA Journal 2012;10(6):2734.
([8]) EFSA Journal 2012;10(11):2970.
([9]) EFSA Journal 2013;11(10):3369.
([10]) EFSA Journal 2015;13(4):4058.

hydrate do not have an adverse effect on animal and human health and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(5) With respect to the impacts on the environment, in particular the drainage and run-off of zinc to surface water, the Authority recommended in its opinion of 8 April 2014 ([1]) to decrease significantly the maximum contents of zinc in complete feed for several target species. However, in order not to risk not meeting the physiological needs of animals also in special life periods or any other negative impacts on animal health, the decrease of zinc contents recommended by the Authority should not be introduced in one step. With the objective of further reductions, feed business operators and research institutes should be encouraged to collect new scientific data about the physiological needs of the different animal species.

(6) The Authority further concluded that Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate are effective sources of zinc. Considering the chemical characteristics of Zinc chelate of amino acids, the Authority recommends its splitting into the following two groups: Zinc chelate of amino acids hydrate and Zinc chelate of protein hydrolysates. Moreover, for Zinc chelate of glycine hydrate two different forms have been assessed, a solid and a liquid one. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report 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 Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(8) As a result of the granting authorisation for 'Zinc acetate dihydrate', 'Zinc oxide', 'Zinc sulphate heptahydrate', 'Zinc sulphate monohydrate', 'Zinc chelate of amino acids hydrate' and 'Zinc chelate of glycine hydrate' by this Regulation, the entries on these substances in Regulations (EC) No 479/2006 and (EC) No 1334/2003 are obsolete and should therefore be deleted.

(9) Commission Regulation (EU) No 335/2010 ([2]) and Commission Implementing Regulations (EU) No 991/2012 ([3]) and (EU) No 636/2013 ([4]) authorised several zinc compounds as nutritional feed additives. In order to take into account the conclusions of the Authority in its opinion of 8 April 2014, which were also the scientific basis for the provisions concerning the total zinc content in compound feed for the additives authorised by this Regulation and which are mainly referring to the environmental impact of feed supplementation with zinc, it is appropriate to align the maximum contents of zinc in Regulation (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 with the provisions of this Regulation as regards the zinc content in compound feed. Regulations (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 should therefore be amended accordingly.

(10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate and the zinc compounds authorised by Regulation (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

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

([1]) EFSA Journal 2014;12(5):3668.
([2]) Commission Regulation (EU) No 335/2010 of 22 April 2010 concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species (OJ L 102, 23.4.2010, p. 22).
([3]) Commission Implementing Regulation (EU) No 991/2012 of 25 October 2012 concerning the authorisation of zinc chloride hydroxide monohydrate as feed additive for all animal species (OJ L 297, 26.10.2012, p. 18).
([4]) Commission Implementing Regulation (EU) No 636/2013 of 1 July 2013 concerning the authorisation of zinc chelate of methionine (1:2) as a feed additive for all animal species (OJ L 183, 2.7.2013, p. 3).

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

Article 2

Amendment to Regulation (EC) No 1334/2003

In the Annex to Regulation (EC) No 1334/2003, from the entry E6 on the element Zinc-Zn the following additives: 'Zinc acetate dihydrate', 'Zinc oxide', 'Zinc sulphate heptahydrate', 'Zinc sulphate monohydrate', 'Zinc chelate of amino acids hydrate', and their chemical formulas and descriptions are deleted.

Article 3

Amendment to Regulation (EC) No 479/2006

In the Annex to Regulation (EC) No 479/2006, the entry E6 on the additive 'Zinc chelate of glycine hydrate' is deleted.

Article 4

Amendment to Regulation (EU) No 335/2010

In the Annex to Regulation (EU) No 335/2010, in the line 3b6.10 the eighth column is replaced by the following:

'Dogs and cats: 200 (total)

Salmonids and milk replacers for calves: 180 (total)

Piglets, sows, rabbits and all fish species other than salmonids: 150 (total)

Other species and categories: 120 (total)'.

Article 5

Amendment to Implementing Regulation (EU) No 991/2012

In the Annex to Implementing Regulation (EU) No 991/2012, in the line 3b609 the eighth column is replaced by the following:

'Dogs and cats: 200 (total)

Salmonids and milk replacers for calves: 180 (total)

Piglets, sows, rabbits and all fish species other than salmonids: 150 (total)

Other species and categories: 120 (total)'.

Article 6

Amendment to Implementing Regulation (EU) No 636/2013

In the Annex to Commission Implementing Regulation (EU) No 636/2013, in the line 3b611 the eighth column is replaced by the following:

'Dogs and cats: 200 (total)

Salmonids and milk replacers for calves: 180 (total)

Piglets, sows, rabbits and all fish species other than salmonids: 150 (total)

Other species and categories: 120 (total)'.

Article 7

Transitional measures

1. Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate and the zinc compounds authorised by Regulation (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 and premixtures containing them, which are produced and labelled before 27 January 2017 in accordance with the rules applicable before 27 July 2016 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 27 July 2017 in accordance with the rules applicable before 27 July 2016 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 27 July 2018 in accordance with the rules applicable before 27 July 2016 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 8

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, 6 July 2016.

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b601	—	Zinc acetate dihydrate	*Additive composition* Zinc acetate dihydrate, as a powder with a minimum content of 29,6 % zinc. *Characterisation of the active substance* Chemical formula: $Zn(CH_3COO)_2 \cdot 2H_2O$ CAS Number: 5970-45-6 *Analytical methods* (1) For the quantification of the zinc acetate dihydrate in the feed additive: — titration with sodium edetate (European Pharmacopoeia Monograph 1482). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (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. 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.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			— EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion. For the quantification of total zinc in feed materials and compound feed: — Commission Regulation (EC) No 152/2009 [2] — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						
3b602	—	Zinc chloride anhydrous	*Additive composition* Zinc chloride anhydrous, as a powder with a minimum content of 46,1 % zinc.	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total)	1. The additive shall be incorporated into feed in the form of a liquid premixture.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			Characterisation of the active substance Chemical formula: $ZnCl_2$ CAS Number: 7646-85-7 *Analytical methods* (1) For the quantification of the zinc chloride anhydrous in the feed additive: — titration with sodium edetate (European Pharmacopoeia Monograph 0110). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion; — ICP-AES CEN method (EN ISO 11885); not for premixtures.				Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (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. 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.	

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						
3b603	—	Zinc oxide	*Additive composition* Zinc oxide, as a powder with a minimum content of 72 % zinc *Characterisation of the active substance* Chemical formula: ZnO CAS Number: 1314-13-2	All animal species	—	—	Dogs and cats: 200 (total)	1. The additive shall be incorporated into feed in the form of a premixture.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			Analytical methods (1) For the quantification of the zinc oxide in the feed additive: — titration with sodium edetate (European Pharmacopoeia Monograph 0252). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion. For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or				Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (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. 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.	

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			— EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						
3b604	—	Zinc sulphate heptahydrate	*Additive composition* Zinc sulphate heptahydrate, as a powder with a minimum content of 22 % zinc. *Characterisation of the active substance* Chemical formula: $ZnSO_4 \cdot 7H_2O$ CAS Number: 7446-20-0 *Analytical methods* (1) For the quantification of the zinc sulphate heptahydrate in the feed additive: — titration with sodium edetate (European Pharmacopoeia Monograph 0111).	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (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. 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.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion. For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
3b605	—	Zinc sulphate monohydrate	*Additive composition* Zinc sulphate monohydrate, as a powder with a minimum content of 34 % zinc. *Characterisation of the active substance* Chemical formula: $ZnSO_4 \cdot H_2O$ CAS Number: 7446-19-7 *Analytical methods* (1) For the quantification of the zinc sulphate monohydrate in the feed additive: — titration with sodium edetate (European Pharmacopoeia Monograph 2159). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (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. 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.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						
3b606	—	Zinc chelate of amino acids hydrate	*Additive composition* Zinc amino acid complex where the zinc and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 10 % zinc.	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Zinc chelate of amino acids may be placed on the market and used as an additive consisting of a preparation.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			Characterisation of the active substance Chemical formula: $Zn(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate. Maximum of 10 % of the molecules exceeding 1 500 Da. *Analytical methods* (1) For the quantification of amino acid content in the feed additive: — ion exchange chromatography method with post-column derivatisation and UV or fluorescence detection: Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.				Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	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. 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.	

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						
3b612	—	Zinc chelate of protein hydrolysates	*Additive composition* Zinc chelate of protein hydrolysates as a powder with a minimum content of 10 % zinc. Minimum of 85 % zinc chelated.	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Zinc chelate of protein hydrolysates may be placed on the market and used as an additive consisting of a preparation.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			Characterisation of the active substance Chemical formula: $Zn(x)_{1-3} \cdot nH_2O$, x = anion of protein hydrolysates containing any amino acid from soya protein hydrolysate. *Analytical methods* (1) For the quantification of protein hydrolysates content in the feed additive: — ion exchange chromatography method with post-column derivatisation and UV or fluorescence detection: Regulation (EC) No 152/2009 (Annex III, F). For the determination of chelated Zinc content in the feed additive: — Fourier Transformed Infrared (FTIR) spectroscopy followed by multivariate regression methods.				Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	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. 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.	

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN/TS 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion. For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
3b607	—	Zinc chelate of glycine hydrate (solid)	*Additive composition* Zinc chelate of glycine, hydrate, as a powder with a minimum content of 15 % zinc. Moisture: maximum 10 %. *Characterisation of the active substance* Chemical formula: $Zn(x)_{1-3} \cdot nH_2O$, x = anion of glycine. *Analytical methods* (1) For the quantification of the glycine content in the feed additive: — ion exchange chromatography method with post-column derivatisation and UV or fluorescence detection: Regulation (EC) No 152/2009 (Annex III, F). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or	All animal species	—	—	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (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. 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.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			— EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion. For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						
3b608	—	Zinc chelate of glycine hydrate (liquid)	*Additive composition* Liquid zinc chelate of glycine, hydrate, with a minimum content of 7 % zinc.	All animal species	—	—	Dogs and cats: 200 (total)	1. The additive shall be incorporated into feed in the form of a premixture.	27 July 2026

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			Characterisation of the active substance Chemical formula: $Zn(x)_{1-3} \cdot nH_2O$, x = anion of glycine. *Analytical methods* (1) For the quantification of the glycine content in the feed additive: — ion exchange chromatography method with post-column derivatisation and UV or fluorescence detection: Regulation (EC) No 152/2009 (Annex III, F). For the quantification of total zinc in the feed additive and premixtures: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES), or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.				Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	2. Zinc chelate of glycine (liquid) may be placed on the market and used as an additive consisting of a preparation. 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. 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.	

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 (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total zinc in feed materials and compound feed: — Regulation (EC) No 152/2009 — Atomic Absorption Spectrometry (AAS); or — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES); or — EN 15621: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP-AES) after pressure digestion.						

(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).