COMMISSION IMPLEMENTING REGULATION (EU) 2016/973

of 17 June 2016

concerning the authorisation of zinc bislysinate as a feed additive for all animal species

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of Zinc chelate of L-Lysinate HCl accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of Zinc chelate of L-Lysinate HCl as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 October 2015 ([2]) that, under the proposed conditions of use, Zinc chelate of L-Lysinate HCl does not have an adverse effect on animal or consumer 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 ([3]) 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 concluded furthermore that Zinc chelate of L-Lysinate HCl may be considered as an efficacious source of zinc for all animal species and recommended to name that substance zinc bislysinate. 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 additive in feed submitted by the Reference Laboratory set up by Article 21 of Regulation (EC) No 1831/2003. The assessment of zinc bislysinate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

(7) 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

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2015;13(11):4267.
([3]) EFSA Journal 2014;12(5):3668.

Article 2

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, 17 June 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									
3b613	—	Zinc bislysinate	*Characterisation of the additive* Powder or granulate with a minimum content of 13,5 % zinc and a minimum content of 85,0 % lysine. Zinc in form of zinc chelate of bislysinate HCl: minimum 85 %. *Characterisation of the active substance* Zinc chelate of bislysinate HCl Chemical formula: $Zn(C_6H_{13}N_2O_2)_2 \times 2HCl \times 2H_2O$ CAS number: 23333-98-4 *Analytical methods* (1) For the quantification of Lysine content in the feed additive and premixtures: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-UV/FD), or — VDLUFA 4.11.6 or EN ISO 17180. For the quantification of total zinc content in the feed additive and premixtures: — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) — EN 15510, 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 the feed in form of a premixture. 2. Zinc bislysinate 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.	8 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 %			
			— Inductively Coupled Plasma Atomic Emission Spectrometry after pressure digestion, (ICP-AES) — EN 15621. For the quantification of total zinc in the feed materials and compound feed: — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) — EN 15510, or — Inductively Coupled Plasma Atomic Emission Spectrometry after pressure digestion, (ICP-AES) — EN 15621, or — Atomic Absorption Spectrometry (AAS) — Commission Regulation (EC) No 152/2009 (2).						

(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).