COMMISSION IMPLEMENTING REGULATION (EU) 2024/265

of 17 January 2024

concerning the authorisation of zinc(II)– betaine complex as a feed additive for all animal species except aquatic animals farmed in marine aquaculture systems

(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(II)– betaine complex. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of zinc(II)– betaine complex as a feed additive for all animal species, to be classified in the additive category 'nutritional additives' and in the functional group 'compounds of trace elements'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 January 2023 ([2]) that, under the proposed conditions of use, zinc(II)– betaine complex is safe for all animal species and consumers, provided that the maximum authorised levels for total zinc in feed are not exceeded. As regards the safety of zinc(II)– betaine complex for the environment, the available data do not allow to conclude on its safety for the marine sediment when that substance is used in sea cages. The Authority further concluded that zinc(II)– betaine complex is considered a skin and respiratory sensitiser, due to the presence of nickel. It is an eye irritant, but it is non-irritant to skin. The Authority concluded that the substance is efficacious as a source of zinc in covering the animals' requirements The Authority did 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 Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that zinc(II)– betaine complex satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2023;21(2):7819

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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.

Article 2

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, 17 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	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 the element (Zn) in mg/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: compounds of trace elements								
3b616	Zinc(II)–betaine complex	*Additive composition* Zinc betaine complex with a minimum of 20 % of zinc and a minimum of 41 % of betaine Nickel: maximum 60 mg/kg Solid form *Characterisation of the active substances* Name: catena-[μ3-sulphato-(trimethylammonio)acetato-zinc(II)] Chemical formula: $[Zn((CH_3)_3NCH_2COO)(SO_4)]n$ Specifications — Minimum of 20 % of zinc — Minimum 41 % betaine, — 9 %–12 % sulphur — Maximum 5 % moisture *Analytical methods* [1] For the quantification of total zinc in the feed additive: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or — Atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total zinc in premixtures: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or	— Dogs — Cats	-	-	200	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 organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing eye and skin protective equipment.	7 February 2034
			— Piglets — Sows — Rabbits — Fish farmed in land-based aquaculture systems, other than salmonids	-	-	150		
			— Calves (milk replacer) — Salmonids farmed in land-based aquaculture systems	-	-	180		
			Other species and categories except aquatic animals farmed in marine aquaculture systems	-	-	120		

ELI: http://data.europa.eu/eli/reg_impl/2024/265/oj

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		— Atomic absorption spectrometry, AAS (ISO 6869) or — Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of total zinc in compound feed: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or — Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of betaine in the feed additive: — High performance liquid chromatography with refraction index detection (HPLC-RI) For the quantification of sulphur and sulfate in the feed additive: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621) Proof of complex formation between zinc, betaine and sulfate: Powder X-ray diffraction (XRD) (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) Stoe Stadi P diffractometer in Guinier geometry using Cu-Kα1 radiation (Johann Gemonochromator) and a Stoe imageplate detector IP-PSD.

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