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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 636/2013

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concerning the authorisation of zinc chelate of methionine (1:2) 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) Methionine-zinc, technically pure, was authorised without a time limit in accordance with Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[(2)] as an amino acid for use on ruminants by Commission Directive 88/485/EEC[(3)]. This feed additive was subsequently entered in the European Union Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for a new use as a compound of trace elements for use for all animal species, requesting that additive to be classified in the additive category ‘nutritional additives’. That application was 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 opinion of 11 December 2012[(4)] that, under the proposed conditions of use, methionine-zinc does not have an adverse effect on animal health, human health or the environment and that it may be considered as an effective source of zinc for all animal species. 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 Regulation (EC) No 1831/2003.

(5) In accordance with the characterisation of the additive by the Authority and the supplementary information by the applicant the appropriate name of the product is zinc chelate of methionine (1:2).

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 636/2013. (See end of Document for details)*

(6) The assessment of that product shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that product 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The product 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

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 636/2013. (See end of Document for details)*

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**
						Maximum content of element (Zn) in mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b611	—	Zinc chelate of methionine (1:2)	*Characterisation of the additive* Powder with a minimum content of 78 % DL-methionine and a zinc content between 17,5 % and 18,5 % *Characterisation of the active substance* Zinc chelate of methionine: Zinc-Methionine 1:2 ($Zn(Met)_2$)	All species		[F1	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)]	1. The additive shall be incorporated into the feed in form of a premixture. 2. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 3. The contribution of the additive to the	22 July 2023

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx

b OJ L 54, 26.2.2009, p. 1.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 636/2013. (See end of Document for details)*

				Chemical formula: $C_{10}H_{20}N_2O_4S_2Zn$ CAS number: 151214-86-7 *Analytical methods*[a]	For the quantification of methionine in feed additive: —	ISO/CD 17180: ion exchange chromatography method with post-column derivatisation and photometric or fluorometric detection.			dietary supply with methionine should be taken into account.
					For the quantification of total zinc in the feed additive and premixtures: —	EN 15510: Inductively Coupled Plasma —			

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx

b OJ L 54, 26.2.2009, p. 1.