



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of a preparation of Zinc-L-selenomethionine as a feed
additive for all animal species**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of zinc-L-selenomethionine 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 nutrition¹, 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) An application was submitted for the modification of the terms of an authorisation of a preparation of zinc L-selenomethionine, which was authorised as an additive in animal nutrition by Commission Implementing Regulation (EU) 2019/49². That modification concerned an increase of the selenium content in the preparation to a range of 2 to 46g Se/kg
- (3) However, the Commission considers that this application actually concerns a new preparation of zinc-L-selenomethionine, with a selenium content in the preparation from 2 to 46g Se/kg. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. The application requests the preparation to be classified in the 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 15 November 2023³ that the preparation of zinc-L-selenomethionine with a minimum content of Se of 40 g/kg is safe for all animal species, the consumer and the environment provided that the maximum selenium supplementation levels authorised in the Union (0.2 mg organic Se/kg complete feed, 0.5 mg total Se/kg complete feed) are respected. The Authority notes that the data assessed cover only a limited concentration range of selenium in the additive (40–46g Se/kg). Since no information was made available for any other preparation of the additive in the range from 2 to 40 g Se/kg, the Authority recommends to consider a new preparation with the following specifications: minimum 40 g Se/kg and maximum 46 g Se/kg. The Authority further

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Implementing Regulation (EU) 2019/49 of 4 January 2019 concerning the authorisation of sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine as feed additives for all animal species (OJ L 10, 14.1.2019, p. 2), ELI: http://data.europa.eu/eli/reg_impl/2019/49/oj.

³ EFSA Journal. 2023;21:e8459.

concluded that the preparation is not irritant to eyes or skin, that it poses a risk by inhalation but no conclusion could be reached regarding dermal sensitisation. As the conditions of use of the additive are the same as the ones for the preparation of zinc-L-selenomethionine already authorised under Implementing Regulation (EU) 2019/49, the Authority also concluded that, the composition of the preparation has no impact on the efficacy of the additive. Furthermore, it did not consider that there is a need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the preparation of zinc-L-selenomethionine are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of zinc-L-selenomethionine with a minimum of 40 g Se/kg of additive and maximum 46 g Se/kg of additive satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation 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.
- (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 **Authorisation**

The preparation 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.

⁴ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8), ELI: <http://data.europa.eu/eli/reg/2005/378/oj>.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN