



2024/3168

19.12.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/3168

of 18 December 2024

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 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) 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) 2019/49 ⁽²⁾. 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 2023 ⁽³⁾ 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 (40–46 g 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 considering a new preparation with the following specifications: minimum 40 g Se/kg and maximum 46 g Se/kg. The Authority further 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.

⁽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.

- (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.

Done at Brussels, 18 December 2024.

For the Commission
The President
Ursula VON DER LEYEN

⁽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>).

ANNEX

| Identification number of the feed 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 (Se) in mg/kg of complete feed with a moisture content of 12 % | | | |
| Category: nutritional additives. Functional group: compounds of trace elements | | | | | | | | |
| 3b818i | Zinc-L-selenomethionine | <p>Characterisation of the additive</p> <p>Solid preparation of Zinc-L-selenomethionine with a selenium content of 40-46 g/kg</p> <p>Characterisation of the active substance</p> <p>Organic selenium in form of zinc L-selenomethionine</p> <p>Chemical formula: C₅H₁₀ClNO₂SeZn</p> <p>Crystalline powder with:</p> <ul style="list-style-type: none"> — L-selenomethionine > 62 %; — selenium > 24,5 %; — zinc > 19 %; and — chloride > 20 % <p>Analytical methods ⁽¹⁾:</p> <p>For the determination of selenomethionine in the feed additive:</p> <ul style="list-style-type: none"> — high performance liquid chromatography with fluorescence detection (HPLC-FLD) <p>For the determination of total selenium in the feed additive:</p> <ul style="list-style-type: none"> — inductively coupled plasma-atomic emission spectrometry (ICP-AES); <p>or</p> <ul style="list-style-type: none"> — inductively coupled plasma-mass spectrometry (ICP-MS) | All species | — | — | 0,50 | <ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 2. The additive shall be incorporated into feed in the form of a premixture. 3. 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 and skin protective equipment. | 8 January 2035 |

| Identification number of the feed 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 (Se) in mg/kg of complete feed with a moisture content of 12 % | | | |
| Category: nutritional additives. Functional group: compounds of trace elements | | | | | | | | |
| | | <p>For the determination of total selenium in premixtures and compound feed:</p> <ul style="list-style-type: none"> — hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion – EN 16159; or — inductively coupled plasma-mass spectrometry (ICP-MS) – EN 17053 <p>For the determination of total zinc in the feed additive:</p> <ul style="list-style-type: none"> — 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) – ISO 6869 | | | | | 4. Maximum supplementation with organic selenium: 0,20 mg Se/kg of complete feed with a moisture content of 12 % | |

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en