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SCIENTIFIC OPINION

Modification of the terms of authorisation of zinc-L-selenomethionine as a feed additive for all animal species (Zinpro Animal Nutrition (Europe), Inc.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of a new preparation of zinc-L-selenomethionine, with selenium content of 4%, as a nutritional feed additive for all animal species. Zinc-L-selenomethionine is already authorised for use in all animal species (3b818). Current authorisation defines the additive as 'Solid preparation of zinc-L-selenomethionine with a selenium content of 1–2 g/kg'. The applicant developed a new preparation of zinc-L-selenomethionine containing a minimum of 40 g Se/kg and seeks to modify the current authorisation. The FEEDAP Panel concluded that the newly proposed preparation is considered safe for all animal species. The FEEDAP Panel recommends adding, to the currently existing authorisation, a new preparation (40–46 g Se/kg) and not the range proposed by the applicant (1–46 g Se/kg), since no characterisation data on the intermediate preparation range (from 2 to 40 g Se/kg) have been provided. The use of the new preparation (minimum 40 g Se/kg) of zinc-L-selenomethionine in animal nutrition is of no concern for consumer safety. The newly proposed preparation presents a risk by inhalation; it is not irritant to eyes or skin. No conclusion can be reached regarding dermal sensitisation. The previous conclusion by the Panel on the safety for the environment remains unchanged. The Panel concluded that the modification request has no impact on efficacy.

KEYWORDS

compounds of trace elements, feed additive, nutritional additives, selenium, zinc-L-selenomethionine

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1 | INTRODUCTION

1.1 | Background and terms of reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from Zinpro Animal Nutrition (Europe), Inc.[2] for the modification of the authorisation of the additive consisting of zinc-L-selenomethionine (Availa® Se), when used as a feed additive for all animal species (category: nutritional additives; functional group: compounds of trace elements).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 13(3) (modification of the authorisation of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 24 March 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of zinc-L-selenomethionine (Availa® Se), when used under the proposed conditions of use (see **Section 3.1.4**).

1.2 | Additional information

The safety and efficacy of zinc-L-selenomethionine and its preparations (Availa® Se) for all animal species have been assessed in 2018 by the FEEDAP Panel (EFSA FEEDAP Panel, 2018a). Zinc-L-selenomethionine is authorised as a nutritional feed additive for all animal species (3b818).[3] The current authorisation defines the additive as 'Solid preparation of zinc-L-selenomethionine with a selenium content of 1–2 g/kg'.

The applicant developed a new preparation and seeks to modify the current authorisation as following: 'Solid preparation of zinc-L-selenomethionine with a selenium content of 1–46 g/kg'.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[4] in support of the request for the authorisation modification for the use of zinc-L-selenomethionine as a feed additive. The dossier was received on 13 December 2022 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00857.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 23 March 2023 to 24 June 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 29 August to 19 September 2023 for which no comments were received.

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2]Zinpro Animal Nutrition (Europe), Inc., Akkerdistel 2E, 5831 PJ, Boxmeer, The Netherlands.

[3]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.

[4]Dossier reference: FEED-2022-5010.

[5]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the zinc-L-selenomethionine in animal feed are valid and applicable for the current application.[7]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of a new preparation of zinc-L-selenomethionine is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3 | ASSESSMENT

The additive zinc-L-selenomethionine is currently authorised[9] as a nutritional additive (functional group: compounds of trace elements) in feed for all animal species; it is authorised as a solid preparation with a selenium content of 1–2 g/kg. The applicant is requesting the modification of the current authorisation to incorporate a wider range for Se content 1–46 g/kg.

3.1 | Characterisation

3.1.1 | Characterisation of the active substance and the additive

The active substance is (S)-2-amino-4-methylselanyl-butanoic acid zinc complex or zinc-L-selenomethionine (Zn-L-SeMet), in the form of chloride. Its chemical formula is $C_5H_{10}ClNO_2SeZn$ and the molecular weight is 295.94 g/mol. Under the current authorisation, the active substance is specified as crystalline powder with L-selenomethionine > 62%, selenium > 24.5%, zinc > 19% and chloride > 20%.

The active substance is produced by chemical synthesis. The active substance is produced by complexing L-selenomethionine (L-SeMet; from chemical synthesis) with zinc to form Zn-L-SeMet complex. The manufacturing process of the active compound and of the formulated additive is described in the technical dossier.[10] The applicant did not propose changes in the manufacturing process of the active substance, with respect to the one that has already been assessed in the previous opinion (EFSA FEEDAP Panel, 2018a).

The additive currently in the market contains 1–2 g Se/kg from the active substance zinc-L-selenomethionine mixed with silicon dioxide (1.62%), vegetable oil (1.02%) and calcium carbonate (97%). The applicant is proposing a new preparation of the additive in which the selenium content is minimum 40 g Se/kg obtained by mixing zinc-L-selenomethionine (14.4%) with silicon dioxide (E551)[11] (85.6%). This new preparation will be referred to as Zn-L-SeMet-4%Se in this opinion.

Analytical data to confirm the Zn-L-SeMet-4%Se specification were provided for five batches,[12] showing the average value for selenium 43.32 g Se/kg (range: 42.20–44.40 g Se/kg). The applicant also provided data on the zinc content, which was on average 36.32 g/kg (range: 34.40–38.20 g/kg) and L-selenomethionine was on average 111.86 g/kg (range: 102.30–117.00 g/kg).

Three batches of the additive were analysed for impurities.[13] Cadmium was below 0.1 mg/kg in all three batches, fluoride ranged from 29 to 31 mg/kg, lead was 0.49 mg/kg (range 0.39–0.59 mg/kg), mercury was below 0.01 mg/kg and arsenic was 0.24 mg/kg (range 0.12–0.36 mg/kg). Dioxins[14] and the sum of dioxins plus dioxin like PCBs concentrations/levels

[7]Evaluation report is available on the EU Science Hub https://joint-research-centre.ec.europa.eu/publications/fad-2016-0056_en

[8]Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[9]COMMISSION IMPLEMENTING REGULATION (EU) 2019/49 of 4 January 2019 concerning the authorisation of sodium selenite, coated granulated sodium selenite and zinc-Lselenomethionine as feed additives for all animal species.

[10]II Manufacturing process.

[11]Currently under re-evaluation.

[12]Annex II 1.6.

[13]Annex II 1.13.

[14]Annex II 1.19.

were on average 0.15 ng WHO-PCDD/F-TEQ/kg and 0.20 ng WHO-PCDD/F-PCB-TEQ/kg (upper bound); non-dioxin-like PCBs were at 0.02 µg/kg additive (upper bound) in all three samples tested.

The analysis of mycotoxins was carried out on three batches.[15] Levels of ochratoxin A and aflatoxins B1, B2, G1 and G2 were all below 1 µg/kg. Microbiological contamination was analysed[16] in three batches by determination of Enterobacteriaceae (< 10 CFU/g), moulds and yeasts (< 10 CFU/g) and *Salmonella* spp. (not present in 25 g).

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns.

3.1.2 | Physical properties of the additive

The additive Zn-L-SeMet-4%Se appears as blue powder with a bulk density[17] of 562 kg/m^3 (range 555–570 kg/m^3).

The dusting potential of three batches of the additive was determined using the Stauber-Heubach method[18] and showed values on average of 2308 mg/m^3 (range 2284–2344 mg/m^3) (mg airborne dust per m^3 of air). The particle size of the dust was analysed by laser diffraction and results showed that on average 83.3% (v/v) of the particles were below the size of 10 µm, while 9.6% (v/v) were below 1 µm. The content of zinc and selenium in the dust was not analysed.

The particle size of the additive was analysed by laser diffraction method;[19] the results showed that on average 6.2% (v/v) of the particles were below 100 µm, 3.93% (v/v) were below 50 µm and 1.23% (v/v) were below 10 µm.

3.1.3 | Stability and homogeneity

For compounds of trace elements, stability studies are generally not required. The applicant did not provide any new data on the stability. The capacity for homogeneous distribution of the additive Zn-L-SeMet-4%Se was studied in premix and in mash and pelleted feed (in 10 subsamples of each matrix). Average content of selenium in premix[20] was 341 mg Se/kg (mineral premix), 55.3 mg Se/kg (starter premix) and 52.4 mg Se/kg (grower premix) and the coefficient of variation (CV) was 3.5%, 3.77 and 4.23, respectively. The average content of selenium in mash feed[21] (starter and grower) was 0.187 mg Se/kg and 0.209 mg Se/kg, respectively, while in pelleted feed, it was 0.193 mg Se/kg; corresponding CVs were 3.7%, 5.8% and 5.0%.

3.1.4 | Conditions of use

Zn-L-selenomethionine is currently authorised to be used in feed for all animal species. It should be used up to a maximum supplementation rate of 0.2 mg Se/kg feed; a total selenium concentration of 0.5 mg/kg feed should not be exceeded. The additive should be incorporated to feed via a premixture.

The applicant did not propose any change in the conditions of use for the new preparation.

3.2 | Safety

The FEEDAP Panel considers that the proposed modification to the terms of authorisation (higher Se concentration in the additive) would not have an impact on the safety for the consumer and the environment since the conditions of use reflect the current maximum limits of supplementation of selenium from all organic sources (0.2 mg/kg complete feed). The same would apply to zinc. The safety for the target animals and the users is assessed below.

3.2.1 | Safety for the target species

The safety of the additive currently authorised was established in a previous opinion (EFSA FEEDAP Panel, 2018a) and the Panel considers that the only aspect which would require a reconsideration of the previous assessment of the safety for target species could be derived from the higher selenium concentration of the additive and the subsequent potential of a less homogeneous distribution of selenium in feed. The data provided in the homogeneity study (see Section 3.1.3) show that the additive distributes homogeneously in the complete feed. Therefore, the exposure of target animals to organic

[15] Annex II 1.25.
[16] Annex II.1.25.
[17] Annex II 1.13.
[18] Annex II 1.31.
[19] Annex II 1.31.
[20] Annex II 4.2 and Supplementary information 2023-10-17.
[21] Supplementary information 2023-10-17.

selenium is not expected to be affected by the use of a product with a higher Se concentration, when it is used under current conditions of use. Therefore, the FEEDAP Panel concludes that the proposed modification in the Se concentration of the additive is safe for all animal species.

3.2.2 | Safety for the user

3.2.2.1 | *Effect on respiratory system*

No specific studies were provided by the applicant regarding the toxicity of the additive on the respiratory system.

The highest measured dusting potential of the additive was 2344 mg/m^3 (see Section 3.1.1). Considering the highest concentrations of 44,400 mg Se/kg and 38,200 mg Zn/kg in the additive, and assuming the same proportion of Se and Zn in the dust as in the additive, it can be calculated that a maximum concentration of 104 mg Se/m^3 and 89.5 mg Zn/m^3 could be released by the dust when handling the additive. Based on particle size analyses of the dust, the respirable fraction could be estimated to be 83.3%.

Thus, the concentration of selenium in the respirable dust would be 87 mg Se/m^3 (83.3% × 104 mg Se/m^3) and for zinc 75 mg/m^3 (83.3% × 89.5 mg Zn/m^3).

The estimated concentration of selenium in the air exceeds by several orders of magnitude internationally accepted proposed thresholds for selenium (0.02 mg/m^3, set by the Deutsche Forschungsgemeinschaft as the maximum concentration in the workplace (Maximale Arbeitsplatz Konzentration, MAK; DFG, 2018). The calculated content of zinc in the air is above the reported maximum concentration limit for the respirable fraction in the workplace of 0.1 mg/m^3 (DFG, 2018); and also, above the TWA of 1 mg/m^3 for zinc chloride or the TWA of 5 mg/m^3 (respirable dust) for zinc oxide (NIOSH, 2007). Consequently, the FEEDAP Panel considers that the additive poses a risk upon inhalation to users.

3.2.2.2 | *Effect on eyes and skin*

Zn-L-SeMet-4%Se was tested for dermal irritancy in a study[22] with New Zealand White rabbits in accordance with OECD TG 404 (2015). From the results of this study, the product should be classified as non-irritant to skin (UN GHS 'No Category').

Zn-L-SeMet-4%Se was tested for eye irritancy in a study[23] with New Zealand White rabbits in accordance with OECD TG 405 (2021). From the results of this study, the product should be classified as non-irritant to eyes (UN_GHS 'No Category').

No data have been provided on the skin sensitisation potential.

3.2.2.3 | *Conclusions on safety for the user*

Zn-L-SeMet-4%Se is not irritant to eyes or skin; no conclusion can be reached regarding dermal sensitisation. Zn-L-SeMet-4%Se poses a risk by inhalation.

3.3 | Efficacy

As the conditions of use of the additive remain the same as the ones already authorised, the Panel considers that the efficacy of the product would not be affected by the proposed modification to the terms of authorisation.

3.4 | Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[24] and good manufacturing practice.

4 | CONCLUSIONS

The FEEDAP Panel concludes that the new preparation Zn-L-SeMet-4%Se 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 EU (0.2 mg organic Se/kg complete feed, 0.5 mg total Se/kg complete feed) are respected.

Zn-L-SeMet-4%Se is not irritant to the eyes or skin, but it poses a risk by inhalation. No conclusion can be reached regarding dermal sensitisation.

The FEEDAP Panel considers that the proposed modification in the composition has no impact on the efficacy of the additive.

[22] Annex III.3.2.

[23] Annex III.3.3.

[24] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

5 | RECOMMENDATION

The FEEDAP Panel notes that data assessed in the present opinion cover only a limited concentration range of selenium in the additive (40–46 g Se/kg). Since no information were made available for any other preparation of the additive in the range from 2 to 40 g Se/kg, the FEEDAP Panel recommends adding to the currently existing authorisation a new preparation with the specifications: minimum 40 g Se/kg and maximum 46 g Se/kg.

ABBREVIATIONS

CAS	Chemical Abstracts Service
CV	coefficient of variation
DM	dry matter
ECHA	European Chemicals Agency
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
MW	molecular weight
NOAEL	no observed adverse effect level

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

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