

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/968****of 16 June 2021****concerning the renewal of the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species, and repealing Regulation (EU) No 335/2010****(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 <sup>(1)</sup>, 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 and renewing such authorisation.
- (2) Zinc chelate of hydroxy analogue of methionine was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EU) No 335/2010 <sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of zinc chelate of hydroxy analogue of methionine as feed additive for all animal species in the additive category 'nutritional additives'. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) It results from the opinion of the European Food Safety Authority ('the Authority') of 18 November 2020 <sup>(3)</sup> that, under the proposed conditions of use, zinc chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded for the additive a risk for the user by inhalation and that it is a skin sensitizer. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The proof of the efficacy of the additive, on which the initial authorisation was based, withstands in a renewal procedure. The Authority 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) The assessment of zinc chelate of hydroxy analogue of methionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed.
- (6) As a consequence of the renewal of the authorisation of zinc chelate of hydroxy analogue of methionine as feed additive, Regulation (EU) No 335/2010 should be repealed.
- (7) The authorisation holder signalled some modifications in the manufacturing process. Since safety reasons do not require the immediate application of these modifications to the conditions of authorisation for zinc chelate of hydroxy analogue of methionine, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EU) No 335/2010 of 22 April 2010 concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species (OJ L 102, 23.4.2010, p. 22).

<sup>(3)</sup> EFSA Journal 2020;18(12):6337.

HAS ADOPTED THIS REGULATION:

*Article 1*

The authorisation of the additive specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is renewed subject to the conditions laid down in that Annex.

*Article 2*

1. Zinc chelate of hydroxy analogue of methionine and premixtures containing this additive, which are produced and labelled before 7 January 2022 in accordance with the rules applicable before 7 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing zinc chelate of hydroxy analogue of methionine, which are produced and labelled before 7 July 2022 in accordance with the rules applicable before 7 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing zinc chelate of hydroxy analogue of methionine, which are produced and labelled before 7 July 2023 in accordance with the rules applicable before 7 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 3*

Regulation (EU) No 335/2010 is repealed.

*Article 4*

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, 16 June 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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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
						Content of element (Zn) in mg/kg of complete feed with a moisture content of 12 %			
<b>Category: nutritional additives. Functional group: compounds of trace elements</b>									
3b610	-	Zinc chelate of hydroxy analogue of methionine	<p><b>Characterisation of the additive:</b> Zinc chelate of hydroxy analogue of methionine containing 17 % zinc and 79 % (2-hydroxy-4-methylthio) butanoic acid. Maximum content of nickel: 1,7 ppm. Solid form.</p> <p><b>Analytical method<sup>(1)</sup>:</b> For the quantification of the hydroxy analogue of methionine content in the feed additive: — Titrimetry, potentiometric titration after oxidation reduction reaction; For the quantification of total zinc in the feed additive: — Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — Atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total zinc in premixtures: — Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — Atomic absorption spectrometry, AAS (ISO 6869) or — Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053);</p>	All species	-	-	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	<ol style="list-style-type: none"> <li>The additive shall be incorporated into feed in the form of a pre-mixture.</li> <li>Zinc chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation.</li> <li>For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by</li> </ol>	7.7.2031

			<p>For the quantification of total zinc in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or</li> <li>— Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or</li> <li>— Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053).</li> </ul>					<p>these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</p>	
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(<sup>4</sup>) 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>