COMMISSION IMPLEMENTING REGULATION (EU) No 445/2013

of 14 May 2013

concerning the authorisation of hydroxy-analogue of 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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of hydroxy-analogue of selenomethionine. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of hydroxy-analogue of selenomethionine, an organic compound of selenium, as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 December 2012 ([2]) that, under the proposed conditions of use, hydroxy-analogue of selenomethionine does not have an adverse effect on animal health, human health or the environment and that its use may be considered as an effective source of selenium 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) The assessment of hydroxy-analogue of selenomethionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) The Authority concluded that the limitation of the supplementation with organic selenium should apply to the already authorised organic selenium compounds, the selenised yeasts, and hydroxy-analogue of selenomethionine. Thus, in case inorganic compounds of selenium are also added to the feed, the supplementation with organic selenium should not exceed 0,2 mg per kg complete feed.

(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 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

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, 14 May 2013.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2013; 11(1):3046.

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
						Content of element (Se) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b814	—	Hydroxy-analogue of selenomethionine	*Characterisation of the additive* Solid and liquid preparation of Hydroxy-analogue of selenomethionine Content of selenium: 18 000 to 24 000 mg Se/kg Organic selenium > 99 % of total Se Hydroxy-analogue of selenomethionine > 98 % of total Se Solid preparation: 5 % Hydroxy-analogue of selenomethionine and 95 % carrier Liquid preparation: 5 % Hydroxy-analogue of selenomethionine and 95 % distilled water *Characterisation of the active substance* Organic selenium from hydroxy-analogue of selenomethionine (R,S-2-hydroxy-4-methylselenobutanoic acid) Chemical formula: $C_5H_{10}O_3Se$ CAS number 873660-49-2 *Analytical method* (1) For the determination of hydroxy analogue of methionine in the feed additive: — High performance liquid chromatography coupled to UV detection at 220 nm (HPLC-UV) For the determination of total selenium in the feed additive: — Inductively coupled plasma mass spectrometry (ICPMS) after microwave digestion with HNO_3/H_2O_2, or — Inductively coupled plasma atomic emission spectrometry (ICPAES) after digestion with HNO_3/HCl	All species	—		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 3. Maximum supplementation with organic selenium: 0,20 mg Se/kg of complete feed with a moisture content of 12 %.	4 June 2023

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 (Se) in mg/kg of complete feed with a moisture content of 12 %			
			For the determination of total selenium in premixtures and feed: — Hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion with HNO_3/H_2O_2 (EN 16159:2012)						

([1]) 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