Commission Implementing Regulation (EU) No 121/2014 of 7 February 2014 concerning the authorisation of L-selenomethionine as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 121/2014

of 7 February 2014

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

(3) That application concerns the authorisation of L-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 2 May 2013[(2)] that, under the proposed conditions of use, L-selenomethionine does not have an adverse effect on animal health, human health or the environment and that its use may be considered as an efficient 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 L-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 that 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 established for other organic compounds of selenium should also apply to L-

selenomethionine. Furthermore, in case different compounds of selenium are added to the feed, the supplementation with organic selenium should not exceed 0,2 mg per kg complete feed.

(7) The applicant delivered supplementary data consequently to the abovementioned opinion of the Authority to prove the stability of the additive once it is incorporated in premixtures containing compounds of trace elements.

(8) 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, 7 February 2014.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 121/2014. (See end of Document for details)*

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**
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b815	—	L-selenomethionine	*Characterisation of the additive* Solid preparation of L-selenomethionine with a selenium content < 40 g/kg *Characterisation of the active substance* Organic selenium in form of L-selenomethionine (2-amino-4-methylselanyl-butanoic acid) from chemical synthesis Chemical formula: $C_5H_{11}NO_2Se$ Analytical methods[a]	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 shall be worn during handling. 3. Technological additives or feed materials included in the preparation of the additive shall ensure a dusting	28 February 2024

a 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