COMMISSION IMPLEMENTING REGULATION (EU) 2015/489

of 23 March 2015

concerning the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645 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 selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645. 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 a preparation 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 3 July 2014 ([2]) that, under the proposed conditions of use, selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645 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 selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645 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 selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645. 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 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

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2014; 12(7):3797.

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, 23 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

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									
3b817	—	Selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645 (Selenised yeast inactivated)	*Characterisation of the additive:* Preparation of organic selenium: Content of selenium: 2 000 to 2 400 mg Se/kg Organic selenium > 98 % of total selenium Selenomethionine > 70 % of total selenium *Characterisation of the active substance:* Selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645 Chemical formula: $C_5H_{11}NO_2Se$ *Analytical method* (1): For the determination of selenomethionine in the feed additive: — reversed phase high performance liquid chromatography with UV detection (RP-HPLC-UV), or — high performance liquid chromatography and inductively coupled plasma mass spectrometry (HPLC-ICPMS) after triple proteolytic digestion. For the determination of total selenium in the feed additive: — inductively coupled plasma atomic emission spectrometry (ICP-AES), or — inductively coupled plasma mass spectrometry (ICPMS).	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 potential < 0,2 mg selenium/m^3 air. 4. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 5. Maximum supplementation with organic selenium: 0,20 mg Se/kg of complete feed with a moisture content of 12 %.	13 April 2025

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 %			
			For the determination of total selenium in premixtures, compound feed and feed materials: hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion (EN 16159:2012).						

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx