Commission Implementing Regulation (EU) No 427/2013 of 8 May 2013 concerning the authorisation of selenomethionine produced by Saccharomyces cerevisiae NCYC R646 as a feed additive for all animal species and amending Regulations (EC) No 1750/2006, (EC) No 634/2007 and (EC) No 900/2009 as regards the maximum supplementation with selenised yeast (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 427/2013

of 8 May 2013

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(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 R646. That 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 selenomethionine, an organic compound of selenium, produced by *Saccharomyces cerevisiae* NCYC R646 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 15 June 2012[(2)] that, under the proposed conditions of use, selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 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 selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 shows that the conditions for authorisation, as provided for in Article 5 of

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 427/2013. (See end of Document for details)*

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 reiterated in its opinion mentioned above the recommendation from its opinion of 15 March 2011[(3)] to limit the maximum supplementation with selenised yeast, an organic selenium compound, to 0,2 mg Se/kg complete feed for reasons of consumer safety. Selenised yeasts are already authorised by Commission Regulations (EC) No 1750/2006[(4)], (EC) No 634/2007[(5)] and (EC) No 900/2009[(6)]. Consequently, these authorisations should be amended in consistency with the Annex to this Regulation. 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) Since further use of selenised yeasts as a feed additive at incorporation rates higher than 0,20 mg Se/kg complete feed may cause a risk to human health, feed materials and compound feed with higher levels of selenised yeasts should be phased out. For practical reasons however, a limited transitional period should be allowed for interested parties to prepare themselves to meet the new requirements.

(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

In column 9 in the Annex to Regulation (EC) No 1750/2006, the text in the line ‘3b8.10’ shall be replaced by the following:

1. The additive shall be incorporated in 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 %..

Article 3

In column 9 in the Annex to Regulation (EC) No 634/2007, the text in the line ‘3b8.11’ shall be replaced by the following:

1. The additive shall be incorporated in 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 %..

Article 4

In column 9 in the Annex to Regulation (EC) No 900/2009, the text in the line '3b8.12' shall be replaced by the following:

1. The additive shall be incorporated in 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 %..

Article 5

The manufacturing of feed containing selenised yeast according to the existing maximum contents in Regulations (EC) No 1750/2006, (EC) No 634/2007 and (EC) No 900/2009 shall be brought in compliance with the new maximum contents as soon as possible and at the latest by 28 July 2013. Feed containing selenised yeast according to the existing maximum contents in Regulations (EC) No 1750/2006, (EC) No 634/2007 and (EC) No 900/2009 may be used up until stocks are exhausted.

Article 6

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, 8 May 2013.

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 427/2013. (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
						Maximum 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									
3b813	—	Selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 (Selenised yeast inactivated)	*Characterisation of the additive* Preparation of organic selenium: Content of selenium: 1 000 to 2 650 mg Se/kg Organic selenium > 98 % of total selenium Selenomethionine > 70 % of total selenium *Characterisation of the active substance* Selenomethionine produced	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	29 May 2023

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