Commission Implementing Regulation (EU) 2019/804 of 17 May 2019 concerning the renewal of the authorisation of organic form of selenium produced by Saccharomyces cerevisiae CNCM I-3060 and of selenomethionine produced by Saccharomyces cerevisiae NCYC R397 as feed additives for all animal species and repealing Regulations (EC) No 1750/2006 and (EC) No 634/2007 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/804

of 17 May 2019

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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 and renewing such authorisation.

(2) The organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 1750/2006[(2)]. Selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 634/2007[(3)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, applications were submitted for the renewal of the authorisation of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species, requesting those additives to be classified in the additive category ‘nutritional additives’. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 5 July 2018[(4)] and 28 November 2018[(5)] that the applicants have provided data demonstrating that the additives comply with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that

the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and the selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 do not have adverse effects on animal health, consumer safety or the environment. It also stated for the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 capacities to be a respiratory sensitizer and hazardous upon inhalation, and for selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 capacities to be an eye and mucosae irritant, and a skin and respiratory 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. Finally, the Authority recommends changing the denomination of the additives.

(5) It is appropriate to update the methods of analysis for selenium and selenomethionine based on the respective recent reports of the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of those additives should be renewed as specified in the Annex to this Regulation.

(7) As a consequence of the renewal of the authorisations of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1750/2006 and (EC) No 634/2007 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and for selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397, 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.

(9) 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 authorisation of the additives 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 The organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060, selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 and premixtures containing these substances, which are produced and labelled before 9 December 2019 in accordance with the rules applicable before 9 June 2019 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substances referred to in point 1, which are produced and labelled before 9 June 2020 in accordance with the rules applicable before 9 June 2019 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 the substances referred to in point 1, which are produced and labelled before 9 June 2021 in accordance with the rules applicable before 9 June 2019 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

Regulations (EC) No 1750/2006 and (EC) No 634/2007 are 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, 17 May 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/804. (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									
3b810	—	Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated	*Additive composition* Preparation of organic selenium: Content of selenium: 2 000 to 2 400 mg Se/kg Organic selenium > 97 to 99 % of total selenium Selenomethionine > 63 % of total selenium *Characterisation of the active substance* Selenomethionine produced by	All species	—		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated	9 June 2029

a 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

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			Saccharomyces cerevisiae CNCM I-3060 Chemical formula: $C_5H_{11}NO_2Se$ *Analytical method*[a] 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				or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 3. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 4. Maximum supplementation with organic selenium: 0,20 mg Se/ kg of complete feed with a moisture content	

a 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