Commission Implementing Regulation (EU) 2020/2117 of 16 December 2020 concerning the renewal of the authorisation of selenomethionine produced by Saccharomyces cerevisiae CNCM I-3399 with the new name 'selenised yeast Saccharomyces cerevisiae CNCM I-3399' as a feed additive for all animal species, and repealing Regulation (EC) No 900/2009 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2117

of 16 December 2020

concerning the renewal of the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 with the new name 'selenised yeast *Saccharomyces cerevisiae* CNCM I-3399' as a feed additive for all animal species, and repealing Regulation (EC) No 900/2009

(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) Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 900/2009[(2)].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 as feed additive for all animal species in the additive category 'nutritional additives'. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) It results from the opinion of the European Food Safety Authority ('the Authority') of 7 May 2020[(3)] that, under the proposed conditions of use, selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded that the additive is a potential dermal 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. The proof of the efficacy of the additive, on which the initial authorisation was based, withstands in

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/2117. (See end of Document for details)*

a renewal procedure. Finally, the Authority recommended changing the denomination of the additive. The Authority 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* CNCM I-3399 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed.

(6) As a consequence of the renewal of the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 as feed additive, Regulation (EC) No 900/2009 should be repealed.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399, 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.

(8) 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 additive 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 Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 and premixtures containing this additive, which are produced and labelled before 6 July 2021 in accordance with the rules applicable before 6 January 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399, which are produced and labelled before 6 January 2022 in accordance with the rules applicable before 6 January 2021 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 selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399, which are produced and labelled before 6 January 2023 in accordance with the rules applicable before 6 January 2021 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

Regulation (EC) No 900/2009 is repealed.

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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, 16 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/2117. (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									
3b812	—	Selenised yeast *Saccharomyces cerevisiae* CNCM I-3399, inactivated	*Additive composition*: Preparation of organic selenium: Content of selenium: 2 000 to 3 500 mg Se/kg Organic selenium > 97 to 99 % of total selenium Selenomethionine > 63 % of total selenium *Characterisation of the active substance*: Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 Chemical formula: $C_5H_{11}NO_2Se$	All species			0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. 3. For users of the additive and premixtures, feed business	6 January 2031

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports