

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1459**of 2 September 2022****amending Implementing Regulation (EU) 2019/804 as regards the terms of authorisation of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 as 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 13(3) 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 an authorisation.
- (2) The use of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2019/804 ⁽²⁾.
- (3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, if modified as proposed by the applicant. That modification consists of increasing the minimum concentration of selenium in the feed additive. The request was accompanied by the relevant supporting data.
- (4) The Authority concluded in its opinion of 10 November 2021 ⁽³⁾ that the modification of the terms of authorisation proposed by the applicant do not modify the conclusions reached in the previous assessments on the safety for the target species, consumers, environment and efficacy of the feed additive. The Authority concluded that the additive is hazardous by inhalation, is not irritant for the eyes, skin and is not a dermal sensitiser. The Authority did 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) In view of the Authority's opinion, the Commission therefore considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) The assessment of the modification to the authorisation proposed by the applicant shows that the conditions for authorisation set out in Article 5 of Regulation (EC) No 1831/2003 are fulfilled.
- (7) Implementing Regulation (EU) 2019/804 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ 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 (OJ L 132, 20.5.2019, p. 28).

⁽³⁾ EFSA Journal 2021;19(12):6979

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Implementing Regulation (EU) No 2019/804, the entry 3b810 for the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 is amended in accordance with the Annex to this Regulation.

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, 2 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 <i>Saccharomyces cerevisiae</i> CNCM I-3060, inactivated	<i>Additive composition</i> 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 <i>Characterisation of the active substance</i> Selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3060 Chemical formula: C ₅ H ₁₁ NO ₂ Se <i>Analytical method</i> (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.	All species	-		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. The directions for use of the additive and premixtures shall indicate the storage and stability conditions. 3. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment. 4. Maximum supplementation with organic selenium: 0,2 mg Se/kg of complete feed with a moisture content of 12 %.	9 June 2029

			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). 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).						
3b810i	-	Selenised yeast <i>Saccharomyces cerevisiae</i> CNCM I-3060, inactivated	<i>Additive composition</i> Preparation of organic selenium: Content of selenium 3 000-3 500 mg Se/kg Organic selenium > 97 to 99 % of total selenium Selenomethionine > 63 % of total selenium <i>Characterisation of the active substance</i> Selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3060 Chemical formula: C₅H₁₁NO₂Se <i>Analytical method (*)</i> For the determination of selenomethionine in the feed additive: — reversed phase high performance liquid chromatography with UV detection (RP-HPLC-UV) or	All species	-		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. The directions for use of the additive and premixtures shall indicate the storage and stability conditions. 3. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	9 June 2029

			— 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). 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).					4. Maximum supplementation with organic selenium: 0,2 mg Se/kg of complete feed with a moisture content of 12 %. 5. The dusting potential of the additive shall ensure a maximal Se exposure of 0,2 mg Se/m³	
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(¹) Details of the analytical methods are available at the following address of the European Union Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en