Commission Implementing Regulation (EU) 2020/377 of 5 March 2020 concerning the authorisation of sodium selenate as a feed additive for ruminants (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/377

of 5 March 2020

concerning the authorisation of sodium selenate as a feed additive for ruminants

(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 sodium selenate as a feed additive for ruminants.

(3) The applicant requested sodium selenate to be classified in the additive category ‘nutritional additives’. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 3 July 2019[(2)] that, under the proposed conditions of use, sodium selenate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additive is considered a skin and eye irritant and a skin and respiratory sensitiser. 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 Authority also concluded that the additive is an efficacious source of selenium for ruminants. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Article 21 of Regulation (EC) No 1831/2003.

(5) The assessment of sodium selenate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/377. (See end of Document for details)*

HAS ADOPTED THIS REGULATION:

Article 1

The substance 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

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, 5 March 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) 2020/377. (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									
3b803		Sodium selenate	*Characterisation of the additive* Sodium selenate, as a powder, with a minimum content of 41 % selenium *Characterisation of the active substance* Disodium selenate Chemical formula: Na_2SeO_4 CAS number 13410-01-0 *Analytical method*[a] For the quantification of total selenium in the feed additive: — For the quantification of total	Ruminants	—		0,50 (total)	1. 26 March 2030 2. 3.	Sodium selenate may be placed on the market and used as an additive consisting of a preparation. The additive shall be incorporated into feed in the form of a premixture. For users of the additive and premixture, feed

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