REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/49

of 4 January 2019

concerning the authorisation of sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine as feed additives 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 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Sodium selenite was authorised without a time limit as a feed additive for all animal species in accordance with Directive 70/524/EEC. This substance was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of sodium selenite as a feed additive for all animal species. In the framework of the re-evaluation an application was submitted also for a coated granulated form of sodium selenite.

(4) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of zinc-L-selenomethionine as a feed additive for all animal species.

(5) The applicants requested that sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine be classified in the additive category 'nutritional additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(6) The European Food Safety Authority ('the Authority') concluded in its opinions of 20 October 2015 ([3]), 28 January 2016 ([4]), 8 March 2016 ([5]) and 20 February 2018 ([6]) that, under the proposed conditions of use, sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine do not have adverse effects on animal health, human health or the environment. With respect to the limitation of the supplementation with organic selenium established for other organic compounds of selenium, the Authority concluded that it should also apply to zinc-L-selenomethionine. Moreover, the Authority concluded that sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine may be considered as efficient sources 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 reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) *EFSA Journal* 2015;13(11):4271.
([4]) *EFSA Journal* 2016;14(2):4398.
([5]) *EFSA Journal* 2016;14(3):4442.
([6]) *EFSA Journal* 2018;16(3):5197.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance sodium selenite, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from 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

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. Sodium selenite and premixtures containing that substance, which are produced and labelled before 3 August 2019 in accordance with the rules applicable before 3 February 2019 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing sodium selenite which are produced and labelled before 3 February 2020 in accordance with the rules applicable before 3 February 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 sodium selenite which are produced and labelled before 3 February 2021 in accordance with the rules applicable before 3 February 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

Entry into force

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, 4 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

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									
3b801		Sodium selenite	*Characterisation of the additive* Sodium selenite, as a powder, with a minimum content of 45 % selenium *Characterisation of the active substance* Sodium selenite Chemical formula: Na_2SeO_3 CAS number 10102-18-8 Einecs number 233-267-9 *Analytical method* (1) For the characterisation of sodium selenite: — Titrimetry — European Pharmacopoeia Monograph 01/2008:1677; and/or — Gravimetry For the quantification of total sodium in sodium selenite: — Atomic Absorption Spectrometry (AAS) - EN ISO 6869:2000; or — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) - EN:15510:2007 For the quantification of total selenium in premixtures feed materials and compound feed: — Hydride Generation Atomic Absorption Spectrometry (HGAAS) after microwave digestion — EN 16159:2012	All species	—		0,50 (total)	1. Sodium selenite may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 3. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eye contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with appropriate personal protective equipment.	3 February 2029

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 %			
3b802		Coated granulated sodium selenite	*Characterisation of the additive* Coated granulated preparation of Sodium selenite with — a selenium content of 1 % - 4,5 % and — coating agents and dispersants (polyoxyethylene (20) sorbitan monolaurate (E 432), glycerol polyethyleneglycol ricinoleate (E 484), polyethyleneglycol 300, sorbitol (E 420ii) or maltodextrin) up to 5 % and — granulating agents (calcium magnesium carbonate, calcium carbonate, corn cobs) up to 100 % w/w. Particles < 50 µm: below 5 % *Characterisation of the active substance* Sodium selenite Chemical formula: Na_2SeO_3 CAS number 10102-18-8 Einecs number 233-267-9 *Analytical method* (1) For the quantification of total selenium in the feed additive (film granulated preparation): — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES); or — Inductively Coupled Plasma Mass Spectrometry (ICP-MS)	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 premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eye contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with appropriate personal protective equipment.	3 February 2029

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 %			
			For the quantification of total sodium in the feed additive (film granulated preparation): — Atomic Absorption Spectrometry (AAS) - EN ISO 6869:2000; or — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) - EN:15510:2007 For the quantification of total selenium in premixtures, feed materials and compound feed: — Hydride Generation Atomic Absorption Spectrometry (HGAAS) after microwave digestion — EN 16159:2012						
3b818	—	Zinc-L-selenomethionine	*Characterisation of the additive* Solid preparation of Zinc-L-selenomethionine with a selenium content of 1-2 g/kg *Characterisation of the active substance* Organic selenium in form of zinc L-selenomethionine Chemical formula: $C_5H_{10}ClNO_2SeZn$ Crystalline powder with L-selenomethionine > 62 %, selenium > 24,5 %, zinc > 19 % and chloride > 20 %	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 premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with appropriate personal protective equipment.	3 February 2029

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 %			
			Analytical method (1) For the determination of selenomethionine in the feed additive: — high performance liquid chromatography with fluorescence detection (HPLC-FLD) For the determination of total selenium in the feed additive: — inductively coupled plasma-atomic emission spectrometry (ICP-AES); or — inductively coupled plasma-mass spectrometry (ICP-MS) For the determination of total selenium in premixtures, feed materials and compound feed: — hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion – EN 16159 For the quantification of total zinc in the feed additive: — inductively coupled plasma-atomic emission spectrometry (ICP-AES) – EN 15510; or — inductively coupled plasma-atomic emission spectrometry after pressure digestion, (ICP-AES) – EN 15621					3. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 4. Maximum supplementation with organic selenium: 0,20 mg Se/kg of complete feed with a moisture content of 12 %.	

(1) 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