Commission Implementing Regulation (EU) 2019/1965 of 26 November 2019 concerning the authorisation of sodium molybdate dihydrate as feed additive for sheep (Text with EEA relevance)

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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 such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Sodium molybdate 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 molybdate dihydrate as a feed additive for sheep.

(4) The applicant requested sodium molybdate dihydrate 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.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 23 January 2019[(3)] that, under the proposed conditions of use, sodium molybdate dihydrate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additive is considered as a skin and eye irritant. 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. Moreover, the Authority concluded that molybdenum supplementation in sheep feed with sodium molybdate dihydrate is considered effective in order to guarantee an adequate balance with copper, when the copper to molybdenum ratio in the diet is in the range 3-10. 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.

(6) The assessment of sodium molybdate dihydrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

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

Authorisation

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 feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1 Sodium molybdate dihydrate and premixtures containing that substance, which are produced and labelled before 18 June 2020 in accordance with the rules applicable before 18 December 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 molybdate dihydrate which are produced and labelled before 18 December 2020 in accordance with the rules applicable before 18 December 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 molybdate dihydrate which are produced and labelled before 18 December 2021 in accordance with the rules applicable before 18 December 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, 26 November 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) 2019/1965. (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
						Content of element (Mo) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b701		Sodium molybdate dihydrate	*Additive composition:* Sodium molybdate dihydrate as a powder with a minimum content of 37 % molybdenum. *Characterisation of the active substance:* Chemical formula: Na_2MoO_4. 2 H_2O CAS number: 10102-40-6 *Analytical methods*[a]: For the quantification of total molybdenum in the feed additive, premixtures, feed materials and	Sheep			2,5 (total)	1. In 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 appropriate organisational measures to address the potential risks by	18.2.2029

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