COMMISSION IMPLEMENTING REGULATION (EU) 2022/565

of 7 April 2022

concerning the authorisation of a preparation of 3-nitrooxypropanol as a feed additive for dairy cows and cows for reproduction (holder of the authorisation: DSM Nutritional Products Ltd, represented in the Union by DSM Nutritional Products Sp. z o.o.)

(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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of 3-nitrooxypropanol. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of 3-nitrooxypropanol as a feed additive for dairy cows and cows for reproduction to be classified in the additive category 'zootechnical additives' and functional group 'substances which favourably affect the environment'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2021 ([2]) that, under the proposed conditions of use, 3-nitrooxypropanol does not have an adverse effect on the health of dairy cows and cows for reproduction, consumer safety or the environment. The Authority concluded that the additive should be considered an irritant to eyes and skin, and 3-NOP may be harmful if inhaled with a potential risk due to exposure by inhalation. 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 risk of inhalation should be addressed by placing the additive granulated on the market with a negligible percentage of inhalable particles. The Authority concluded that the additive has the potential to reduce enteric methane production in dairy cows and cows for reproduction. The Authority does 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) The assessment of 3-nitrooxypropanol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance 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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(11):6905.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'substances which favourably affect the environment', 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, 7 April 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
						mg active substance/kg of complete feed with moisture content 12 %			
Category: zootechnical additives. Functional group: substances which favourably affect the environment. (reduction of enteric methane production)									
4c1	DSM Nutritional Products Ltd represented in the Union by DSM Nutritional Products Sp. z o.o.	3-nitrooxypropanol	*Additive composition* Preparation with a minimum of 10 % of 3- nitrooxypropanol Particles < 50 µm: below 0,5 % Particles < 10 µm: 0 % Granular powder *Characterisation of the active substance* 3- nitrooxypropanol (Propan-1,3-diol-mononitrate) Chemical formula: $C_3H_7NO_4$ CAS number: 100502-66-7 *Analytical method* (1) For the quantification of 3-nitrooxypropanol in the feed additive, premixtures and compound feed: — reversed phase high performance liquid chromatography with spectrophotometric detection (HPLC-UV)	Dairy cows and cows for reproduction	-	53	80	1. 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 inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	28 April 2032

(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