COMMISSION IMPLEMENTING REGULATION (EU) 2021/507

of 23 March 2021

concerning the renewal of the authorisation of pyridoxine hydrochloride (vitamin B_6) as a feed additive for all animal species and repealing Implementing Regulation (EU) No 515/2011

(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 and renewing such authorisation.

(2) Pyridoxine hydrochloride (vitamin B_6) was authorised for 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 515/2011 ([2]).

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of pyridoxine hydrochloride as a feed additive for all animal species, requesting the additive to be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 ([3]) that the applicant has provided evidence that the additive complies with the existing conditions of authorisation. The Authority concluded that pyridoxine hydrochloride under the current authorised conditions of use does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is non-irritant to skin and eyes and is not a skin sensitiser but it may cause photosensitisation and in the absence of inhalation toxicity studies, adverse effects in the respiratory tract could not be fully excluded. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to the users of the additive. The Authority also concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

(5) The assessment of pyridoxine hydrochloride shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.

(6) As a consequence of the renewal of the authorisation of pyridoxine hydrochloride as a feed additive, Implementing Regulation (EU) No 515/2011 should be repealed.

(7) 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) No 515/2011 of 25 May 2011 concerning the authorisation of vitamin B_6 as a feed additive for all animal species (OJ L 138, 26.5.2011, p. 40).

([3]) *EFSA Journal* 2020;18(11):6289.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemical well-defined substances having a similar effect' for all animal species, is renewed subject to the conditions laid down in that Annex.

Article 2

Implementing Regulation (EU) No 515/2011 is repealed.

Article 3

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, 23 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives **Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect**								
3a831	'Pyridoxine hydrochloride' or 'vitamin B_6'	*Additive composition* Pyridoxine hydrochloride $C_8H_{11}NO_3 \cdot HCl$ Purity criteria: not less than 98,5 % *Characterisation of active substance* Pyridoxine hydrochloride *Analytical method* (1) For the determination of pyridoxine hydrochloride (Vitamin B_6) in the feed additive: — Titration with perchloric acid (Ph. Eur. 10th edition, monograph 0245) For the determination of pyridoxine hydrochloride (Vitamin B_6) in premixtures: — Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) - VDLUFA Bd.III, 13.9.1 method For the determination of pyridoxine hydrochloride (Vitamin B_6) in feedingstuffs and water: — Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) – method based on EN14164:2008	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and in water shall be indicated. 2. Pyridoxine hydrochloride or vitamin B_6 may be used also via water for drinking. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. 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.	13 April 2031

(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