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

(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) Vitamin B_6 was authorised without time limit as a feed additive for use in all animal species by Directive 70/524/EEC as part of the group 'Vitamins, provitamins and chemically well-defined substances having similar effect'. The additive 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 of that Regulation, an application was submitted for the re-evaluation of vitamin B_6 as a feed additive for all animal species, requesting it 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 9 November 2010 that, under the proposed conditions of use, vitamin B_6 does not have an adverse effect on animal health, consumer health or the environment ([3]). It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(5) The assessment of vitamin B_6 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the additive should be authorised as specified in the Annex to this Regulation.

(6) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to permit a transitional period for the use of existing stocks of the premixtures and compound feed containing this additive.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' is authorised as additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Feed containing vitamin B_6 labelled in accordance with Directive 70/524/EEC or Regulation (EC) No 1831/2003 may continue to be placed on the market and used until stocks are exhausted.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) EFSA Journal 2010;8(12):1917.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 May 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
Nutritional additives: Vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a831	Vitamin B_6/ pyridoxine hydrochloride	*Active substance* pyridoxine hydrochloride $C_8H_{11}NO_3$.HCl Purity criteria: not less than 98,5 % *Analytical methods* (1) 1. For the determination of vitamin B_6 in feed additives: European Pharmacopoeia monograph 0245 – 7th edition) 2. For the determination of vitamin B_6 in premixtures: Reversed phase high performance liquid chromatography coupled with UV detector (RP-HPLC-UV) (2)	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting and in water. 2. Vitamin B_6/pyridoxine hydrochloride may be used also via water for drinking. 3. For user safety: breathing protection, safety glasses and gloves shall be worn during handling.	15 June 2021

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx
(2) VDLUFA, Bd III, 13.9.1.