SCHEDULE 4

Regulation 3

Renewal of authorisation of Pyridoxine hydrochloride (vitamin B_6) (identification number 3a831) as a feed additive for all animal species

The substance Pyridoxine hydrochloride (vitamin B_6), belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is authorised as an additive in animal nutrition in accordance with the specifications in the following table(**1**).

Additive	Pyridoxine hydrochloride (Vitamin B_6)
Identification number of the additive	3a831
Authorisation holder[(1)]	
Additive category	Nutritional additives
Functional group	Vitamins, pro-vitamins and chemically well-defined substances having similar effect.
Additive composition	Pyridoxine hydrochloride with a purity criteria not less than 98.5%.
Characterisation of the active substance(s)	— Pyridoxine hydrochloride: $C_8H_{11}NO_3 \cdot HCl$ — CAS no:58-56-0[(2)]. — EINECS no:200-386-2[(3)].
Analytical methods[(4)]	For determination of pyridoxine hydrochloride (vitamin B_6) in the feed additive: — Titration with perchloric acid (Ph. Eur. 10th edition, monograph 0245[(5)]).
	For determination of pyridoxine hydrochloride (Vitamin B_6) in premixtures: — Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) in accordance with VDLUFA Method Book, Volume III, (3rd edition 1976, revised), Method No.13.9.1[(6)].
	For determination of pyridoxine hydrochloride (Vitamin B_6) in feed and water: — Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) in accordance with BS EN 14164:2014[(7)].
Species or category of animal	All animal species.
Maximum age	Not applicable
Minimum content[(8)]	No minimum
Maximum content[(8)]	No maximum

(**1**) This authorisation is a renewal of the authorisation granted under Commission Implementing Regulation (EU) 515/2011. That Regulation is revoked by regulation 11 of these Regulations.

Other provisions	1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and in water must be indicated. 2) Pyridoxine hydrochloride (Vitamin B_6) may be used via water for drinking.

(1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.

(2) This is a reference to the CAS Registry Number assigned to this additive by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry.

(3) The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1.

(4) Details of the analytical methods set out in the document referenced "JRC.DG.D.6/CvH/GB/ag/ARES(2011)356822" and last updated 6th June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0139.

(5) European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 10th edition. Published 1st July 2019 (ISBN 9789999146111).

(6) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method book, Volume III, 6th Supplement, 2006, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6) is available at the following address: Method book Volume III Feedingstuffs (vdlufa.de). For access to a translated version of Part 13.9.1 may be obtained from the Food Standards Agency, Foss House, Kings Pool, 1-2 Peasholm Green, York, YO1, 7PR.

(7) BS EN 14164:2014 *"Foodstuffs. Determination of vitamin B6 by high performance chromatography"*. Published by the British Standards Institution on 30th June 2014 (ISBN 978 0 580 77941 1). Available from the British Standards Institution https://knowledge.bsigroup.com.

(8) Content of Pyridoxine HCl (Vitamin B_6): mg of additive/kg of complete feed with a moisture content of 12%.