COMMISSION IMPLEMENTING REGULATION (EU) 2019/9

of 3 January 2019

concerning the authorisation of betaine anhydrous as a feed additive for food-producing animals except rabbits

(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.

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

(3) That application concerns the authorisation of betaine anhydrous as a feed additive for food-producing animals to be classified in the additive functional group 'vitamins, provitamins and chemically well-defined substances having a similar effect'. Subsequently, the applicant withdrew the application for rabbits.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 June 2018 ([2]) that, under the proposed conditions of use, betaine anhydrous does not have adverse effects on animal health, human health or the environment. The Authority concluded that betaine anhydrous has a nutritional role and is an effective source of betaine with a potential to be efficacious in all animal species.

(5) The Authority further noted that the solid form has the potential to generate dust; therefore, exposure by inhalation cannot be excluded. In addition, the Authority stated that betaine anhydrous should be considered hazardous by inhalation, irritant to skin, eyes and mucous membranes and a skin sensitiser. Consequently, appropriate protective measures should be taken with respect to the handling of the solid form of betaine anhydrous.

(6) The Authority concluded that the liquid form of betaine anhydrous contains a high proportion of unknown material; therefore, it is not possible to conclude on its safety. Consequently, only the solid form should be authorised.

(7) 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.

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

(9) 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 'vitamins, provitamins and chemically well-defined substances having a similar effect', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2018;16(7):5335

Article 2

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, 3 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, provitamins and chemically well-defined substances having a similar effect									
3a921i	AB Vista Iberia S.L.	Betaine anhydrous produced from genetically modified sugar beet	*Additive composition* Betaine anhydrous *Characterisation of the active substance* Betaine C5H11NO2 CAS number: 107-43-7 Betaine anhydrous, crystalline solid form, produced by extraction from genetically modified KM-ØØØH71-4 sugar beet. Purity criteria: min. 97 % (on anhydrous basis) *Method of Analysis* (1) For the determination of betaine anhydrous (expressed as total betaine) in the *feed additive, premixtures, and feedingstuffs*. High Performance Liquid Chromatography method with refractive index detector (HPLC-RI).	Food-producing animals except rabbits	—	—		1. Betaine anhydrous may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, the storage and stability to heat treatment shall be indicated. 3. On the label of the additive and the premixture the following shall be indicated 'Recommended not to exceed levels of: 2 000 mg of betaine/kg of complete feed (with a moisture content of 12 %)'. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. 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, safety glasses and gloves.	4 August 2028

(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