COMMISSION IMPLEMENTING REGULATION (EU) 2015/1060

of 2 July 2015

concerning the authorisation of betaine anhydrous and betaine hydrochloride as feed additives 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) Betaine anhydrous and betaine hydrochloride were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, 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 thereof, three applications were submitted for the re-evaluation of betaine anhydrous and betaine hydrochloride and preparations of these substances as feed additives for all animal species and, in accordance Article 7 of that Regulation, for a new use in water for drinking. The applicants requested these additives to be classified in the additive category 'nutritional additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) Genetically modified sugar beet KM-ØØØH71-4 and feed produced from it were authorised to be placed on the market by Commission Decision 2007/692/EC ([3]). In accordance with Article 9(6) of Regulation (EC) No 1831/2003 the authorisation of betaine anhydrous produced from genetically modified sugar beet KM-ØØØH71-4 is to include the name of the holder of the authorisation 'Trouw Nutritional International BV' and the unique identifier attributed to the genetically modified organism (GMO).

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 April 2013 and 18 April 2013 ([4]) that under the proposed conditions of use in feed, betaine anhydrous and betaine hydrochloride do not have adverse effects on animal health, human health or the environment.

(6) The Authority further concluded that betaine anhydrous and betaine hydrochloride have the potential to be efficacious for all animal species. The Authority also concluded that no safety concerns would arise for users. 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 additives in feed and water submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of betaine anhydrous and betaine hydrochloride shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation. Maximum recommended contents of supplementation of betaine anhydrous and betaine hydrochloride in feedingstuffs and water for drinking should be set up.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Decision 2007/692/EC of 24 October 2007 authorising the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 283, 27.10.2007, p. 69).
([4]) *EFSA Journal 2013;11(5):3209;EFSA Journal 2013;11(5):3210;EFSA Journal 2013;11(5):3211.*

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) KM-ØØØH71-4 sugar beet is authorized to be used in the production of foods, food ingredients and feed for a period of 10 years from the date of the notification of Decision 2007/692/EC. That decision was notified to the authorization holders on 23 October 2007. The period of authorization of betaine anhydrous produced from KM-ØØØH71-4 sugar beet as a feed additive should not be longer than the period of authorization of KM-ØØØH71-4 sugar beet.

(10) 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

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 23 January 2016 in accordance with the rules applicable before 23 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 23 July 2016 in accordance with the rules applicable before 23 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 July 2017 in accordance with the rules applicable before 23 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

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, 2 July 2015.

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 % or mg of active substance/l of water			
Category of nutritional additives. Functional group: vitamins, provitamins and chemically well-defined substances having a similar effect									
3a920	—	Betaine anhydrous	*Additive composition:* Betaine anhydrous *Characterisation of the active substance* Betaine $C_5H_{11}NO_2$ CAS number: 107-43-7 Betaine anhydrous, produced by chemical synthesis or by extraction from sugar beet molasses or vinasses by-products of sugar production. Purity criteria: betaine anhydrous (solid form) min. 97 % (on anhydrous basis). Betaine anhydrous liquid form min 47 %. *Method of Analysis* (1) For the determination of betaine anhydrous in the *feed additive, premixtures, feedingstuffs and water*: High- Performance Liquid Chromatography method with refractive index detector (HPLC-RI).	All animal species	—	—	—	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, indicate the storage and stability conditions. 3. The additive may be used in water for drinking. 4. Recommended not to exceed supplemental levels of: 2 000 mg of betaine/kg of complete feed (with a moisture content of 12 %) or 1 000 mg of betaine/l of water for drinking for poultry, 700 mg of betaine/l of water for drinking for pigs and 250 mg of betaine/l of water for drinking for calves for rearing. 5. If simultaneous use of betaine supplementation in feed and water for drinking, caution should be exercised no to exceed overall recommended levels, taking into account inherent levels in the feed. 6. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	23.7.2025

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 % or mg of active substance/l of water			
3a921	Trouw Nutrition International BV	Betaine anhydrous produced from genetically modified sugar beet.	*Additive composition* Betaine anhydrous *Characterisation of the active substance* Betaine $C_5H_{11}NO_2$ CAS number: 107-43-7 Betaine anhydrous, 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 in the *feed additive, premixtures, feedingstuffs and water*: High Performance Liquid Chromatography method with refractive index detector (HPLC-RI).	All animal species	—	—	—	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, indicate the storage and stability conditions. 3. The additive may be used in water for drinking. 4. Recommended not to exceed supplemental levels of: 2 000 mg of betaine/kg of complete feed (with a moisture content of 12 %) or 1 000 mg of betaine/l of water for drinking for poultry, 700 mg of betaine/l of water for drinking for pigs and 250 mg of betaine/l of water for drinking for calves for rearing. 5. If simultaneous use of betaine supplementation in feed and water for drinking, caution should be exercised no to exceed overall recommended levels, taking into account inherent levels in the feed. 6. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	23.10.2017

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 % or mg of active substance/l of water			
3a925	—	Betaine hydrochloride	*Additive composition* Betaine hydrochloride. *Characterisation of the active substance* Betaine hydrochloride. Chemical formula: $C_5H_{11}NO_2 \cdot HCl$ CAS number: 590-46-5 Betaine hydrochloride, solid form, produced by chemical synthesis. Purity criteria: min. 98 % (on anhydrous basis). *Method of Analysis* (1) — For the determination of betaine hydrochloride in the feed additive: 1. Titration with perchloric acid (US Pharmacopeia 31, Betaine hydrochloride monograph.); or 2. High Performance Liquid Chromatography method with refractive index detector (HPLC-RI). — For the determination of betaine hydrochloride in premixtures, feedingstuffs and water: High-Performance Liquid Chromatography method with refractive index detector (HPLC-RI).	All animal species	—	—	—	1. Betaine hydrochloride 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, indicate the storage and stability conditions. 3. The additive may be used in water for drinking. 4. Recommended not to exceed supplemental levels of: 2 000 mg of betaine/kg of complete feed (with a moisture content of 12 %) or 1 000 mg of betaine/l of water for drinking for poultry, 700 mg of betaine/l of water for drinking for pigs and 250 mg of betaine/l of water for drinking for calves for rearing. 5. If simultaneous use of betaine supplementation in feed and water for drinking, caution should be exercised no to exceed overall recommended levels, taking into account inherent levels in the feed. 6. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	23.7.2025

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports