COMMISSION IMPLEMENTING REGULATION (EU) 2015/722

of 5 May 2015

concerning the authorisation of taurine as a feed additive for *Canidae, Felidae, Mustelidae* and carnivorous fish

(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) Taurine was authorised without a time limit in accordance with Directive 70/524/EEC as feed additive on all animal species. This substance 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 thereof, an application was submitted for the re-evaluation of taurine and preparations of taurine as a feed additive for all animal species and, in accordance with Article 7 of that Regulation, for a new use in water for drinking. The applicant requested this additive to be classified in the additive category 'nutritional additives'. That 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 22 May 2012 ([3]) that for use in diet for cats, dogs and carnivorous fish, synthetic taurine is considered efficacious. The historical use of diets containing up to 20 % feedingstuffs of animal origin led to the conclusion that up to 0,2 % taurine in complete feedingstuffs is tolerated by all animal species. The Authority recommends that taurine should no longer be authorised for use in poultry, pigs and ruminants. The Authority concluded that under the proposed conditions of use in feed and in water for drinking, taurine does not have adverse effects on animal health, human health or the environment.

(5) The Authority further 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.

(6) The conclusions for cats and dogs can be extrapolated to species of the same family that is to *Felidae* and *Canidae*, as they are physiologically related species in terms of gastrointestinal function.

(7) *Mustelidae* belongs to the order *Carnivora* as *Felidae* and *Canidae*. *Mustelidae* are carnivorous species and many of them obligate carnivorous. They require taurine and its precursors methionine or cysteine in the diet to maintain the normal taurine concentrations in the body. Traditional sources for taurine are muscle tissue, brain or viscera. Since heat processing and the use of alternative sources of protein (with low content of this amino acid) reduce the availability of taurine and its precursors in feeds, there is a historical use of diets containing taurine as a feed additive to ensure that the taurine requirements are satisfied for *Mustelidae*.

(8) The assessment of taurine 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 substance should be authorised as specified in the Annex to this Regulation.

([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]) *EFSA Journal 2012;10(6):2736*.

(9) 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.

(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 substance 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 an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1. The substance specified in the Annex and premixtures containing that substance which are produced and labelled before 26 November 2015 in accordance with the rules applicable before 26 May 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 substance as specified in the Annex which are produced and labelled before 26 November 2015 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for carnivorous fish.

3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 26 May 2017 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for *Canidae, Felidae* and *Mustelidae*.

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, 5 May 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 the active substance/l of water			
Category of nutritional additives. Functional group: vitamins, provitamins and chemically well-defined substances having a similar effect									
3a370	—	Taurine	*Additive composition* Taurine *Active substance* Taurine IUPAC name: 2-amino-ethanesulfonic acid $C_2H_7NO_3S$ CAS number: 107-35-7 Taurine solid form, produced by chemical synthesis: min. 98 %. *Method of Analysis* (1) For the determination of taurine in feed additive: ion-exchange chromatography with post column ninhydrin derivatisation (European Pharmacopoeia method for the determination of amino acids (Ph. Eur. 6.6, 2.2.56 Method 1)). For the determination of taurine in premixtures and feedingstuffs: ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Commission Regulation (EC) No 152/2009 (Annex III, F), or Reverse Phase High- Performance Liquid Chromatography (RP-HPLC) coupled to fluorescence detector (AOAC 999.12).	*Canidae, Felidae, Mustelidae* and carnivorous fish	—	—	—	1. Taurine 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 storage and stability conditions. 3. Recommended levels for maximum content in mg of taurine/kg of complete feedingstuff with a moisture content of 12 %: — Felidae: 2 500 — Carnivorous fish: 25 000 — Canidae and Mustelidae: 2 000. 4. For safety: breathing protection, safety glasses and gloves shall be worn during handling. 5. The additive may be used in water for drinking.	26 May 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 the active substance/l of water			
			For the determination of taurine in water: Liquid Chromatography coupled to UV or fluorescence detector (AOAC 997.05).						

([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