Commission Implementing Regulation (EU) 2018/249 of 15 February 2018 concerning the authorisation of taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species and L-cysteine hydrochloride monohydrate for all species except cats and dogs (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/249

of 15 February 2018

concerning the authorisation of taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species and L-cysteine hydrochloride monohydrate for all species except cats and dogs

(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) The substances taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances 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, an application was submitted for the re-evaluation of the substances concerned produced by fermentation, protein hydrolysis and chemical synthesis as feed additives for all animal species. The applicant requested those additives be classified in the additive category 'sensory 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 9 April 2014[(3)] that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The lack of information on the production strains does not allow concluding on the substances concerned produced by fermentation. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for the use of the substances concerned in water for drinking.

(5) The Authority further concluded that, in the absence of data, the substances concerned should be considered as irritating to skin and eyes and as skin sensitisers. The Authority also considered that the substances concerned are irritating to the respiratory system and have the potential to produce hazardous dust. Consequently, appropriate protective measures should be taken. 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 submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied except for the substances concerned produced by fermentation. The lack of information on the production strains does not allow assessing their safety. Accordingly, the use of the substances concerned produced by chemical synthesis and protein hydrolysis should be authorised as specified in the Annex to this Regulation.

(7) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.

(8) The fact that the use of the substances concerned in water for drinking is not authorised does not preclude their use in compound feed which is administered via water.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/249. (See end of Document for details)*

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1 The substances taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, and premixtures containing those substances, which are produced and labelled before 15 December 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 15 September 2019 in accordance with the rules applicable before 15 March 2018 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 Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 15 September 2020 in accordance with the rules applicable before 15 March 2018 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

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/249. (See end of Document for details)*

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: Sensory additives. Functional group: Flavouring compounds									
2b16056	—	Taurine	*Additive composition* Taurine *Characterisation of the active substance* Taurine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: $C_2H_7O_3NS$ CAS number 107-35-7 FLAVIS No 16.056 *Method of analysis*[a] For identification of taurine	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. On the label of the additive the following	15.3.2028

a 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

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/249. (See end of Document for details)*

			in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of taurine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Commission Regulation (EC) No 152/2009[b] (Annex III, part F).				shall be indicated: Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level suggested on the label of the

a 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

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).