EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species

(Text with EEA relevance)

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(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 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, an application was submitted for the re-evaluation of the substances concerned 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 Authority has already concluded that, since the substances concerned are efficacious

[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 2014;12(5):3670.

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, however, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.

(5) Restrictions and conditions should be provided for to allow for better control. Since safety reasons do not require the setting of a maximum content taking into account the re-evaluation performed by the Authority, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and on the labelling of feed materials and compound feed.

(6) The Authority concluded that, in the absence of data, the substances concerned should be considered as irritating to skin and eyes and skin sensitisers. The Authority recognises 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.

(7) 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 those substances concerned produced by fermentation. The lack of information on the production strains does not allow to assess their safety. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

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

(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 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
Denial

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, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid produced by fermentation is denied.

Article 3
Transitional Measures

1. The substances specified in the Annex and the substances mentioned in article 2, and premixtures containing those substances, which are produced and labelled before [9 *months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 specified in the Annex and the substances mentioned in Article 2 which are produced and labelled before [*18 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 specified in the Annex and the substances mentioned in Article 2 which are produced and labelled before [*30 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 4
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,

For the Commission
The President
Jean-Claude JUNCKER