COMMISSION IMPLEMENTING REGULATION (EU) 2022/1266

of 20 July 2022

concerning the authorisation of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 as a feed additive 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.

(2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of monosodium glutamate as a feed additive for all animal species, to be classified in the category 'sensory additives' and in the functional group 'flavouring compounds'.

(4) The applicant requested the additive to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 in water for drinking should not be allowed.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 November 2021 ([2]) that, under the proposed conditions of use, monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 does not have adverse effects on animal health, human health or the environment. The Authority concluded in the opinion that the additive is not toxic by inhalation, is not irritant to skin or eyes and is not a dermal sensitiser. The Authority further concluded, that monosodium glutamate is efficacious for contributing to the flavour of feed. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

(7) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(8) The fact that monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed which is administered via water.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2021;19(12):6982.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 20 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b621i	Monosodium glutamate	*Additive composition:* Monosodium glutamate *Characterisation of the active substance:* Monosodium L-glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 Purity: ≥ 99 % Chemical formula: $C_5H_8NaNO_4 \bullet H_2O$ CAS number: 6106-04-03 Einecs number: 205-538-1 *Analytical method* (1): For the identification of monosodium L-glutamate in the feed additive: — Food Chemical Codex 'Monosodium L-glutamate monograph' For the quantification of monosodium L-glutamate in the feed additive: — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)	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 conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feeding stuff with a moisture content of 12 %: 25 mg.' 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 on the label of the premixture would result in exceeding the level referred to in point 3.	10.8.2032

		For the quantification of monosodium L-glutamate in premixtures: — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) [2]						

[1] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

[2] 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).