

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1420**of 22 August 2022****concerning the authorisation of L-glutamic acid and monosodium glutamate produced by *Corynebacterium glutamicum* NITE BP-01681 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-glutamic acid and monosodium glutamate produced by *Corynebacterium glutamicum* NITE BP-01681. 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 L-glutamic acid and monosodium glutamate produced by *Corynebacterium glutamicum* NITE BP-01681 as feed additives for all animal species, to be classified in the categories 'nutritional additives' and 'sensory additives'.
- (4) The applicant requested the feed additive to be authorised for use also 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 *Corynebacterium glutamicum* KCCM 80188 in water for drinking should not be allowed. The fact that the additive is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed administered via water.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 January 2022 ⁽²⁾ that, under the proposed conditions of use, L-glutamic acid and monosodium glutamate produced by *Corynebacterium glutamicum* NITE BP-01681 do not have adverse effects on animal health, consumer safety or the environment. It also concluded that these substances are neither considered irritant to skin or eyes, nor dermal sensitisers, but are considered a risk by inhalation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that these substances have the potential to be efficacious as nutritional additives and as flavouring compounds in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It 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 L-glutamic acid and monosodium glutamate produced by *Corynebacterium glutamicum* NITE BP-01681 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2022;20(3):7156.

- (7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (8) 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

1. The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.
2. The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as additives 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, 22 August 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: nutritional additives.

Functional group: amino acids, their salts and analogues

2b620i	L-Glutamic acid	<i>Additive composition</i> L-Glutamic acid <i>Characterisation of the active substance</i> L-Glutamic acid produced by <i>Corynebacterium glutamicum</i> NITE BP-01681 Purity: ≥ 98 % Chemical formula: C₅H₉O₄N CAS number: 56-86-0 Einecs number: 200-293-7 <i>Analytical method ⁽¹⁾</i> For the identification of L-glutamic acid in the feed additive: — Food Chemical Codex monographs: 'L-Glutamic acid' For the quantification of glutamic acid in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or	All animal species	-	-	-	1. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection. 4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-glutamic acid, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.'	12 September 2032
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		— Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For the quantification of glutamic acid in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of glutamic acid in feedingstuffs: — Ion exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)						
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⁽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

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**

2b620i	L-Glutamic acid	<i>Additive composition</i> L-Glutamic acid <i>Characterisation of the active substance</i> L-Glutamic acid produced by <i>Corynebacterium glutamicum</i> NITE BP-01681 Purity: ≥ 98 % Chemical formula: C₅H₉O₄N CAS number: 56-86-0 Eines number: 200-293-7 <i>Analytical method</i> (1) For the identification of L-glutamic acid in the feed additive: — Food Chemical Codex monographs: 'L-Glutamic acid' For the quantification of glutamic acid in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — 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 premixture, the storage conditions and the 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 of complete feed 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 on the label of the premixture would result in exceeding the level of active substance in complete feed referred to in point 3. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the	12 September 2032
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		For the quantification of glutamic acid in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)					additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection.	
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⁽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

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: nutritional additives.**Functional group: amino acids, their salts and analogues**

2b621ii	Monosodium glutamate	<i>Additive composition</i> Monosodium glutamate <i>Characterisation of the active substance</i> Monosodium glutamate produced by <i>Corynebacterium glutamicum</i> NITE BP-01681 Purity: ≥ 99 % Chemical formula: C₅H₈NaNO₄·H₂O CAS number: 6106-04-3 Eines number: 205-538-1 <i>Analytical method</i> (1) For the identification of monosodium L-glutamate monohydrate in the feed additive: — Food Chemical Codex monographs: 'Monosodium L-glutamate' For the quantification of monosodium glutamate in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)	All animal species	-	-	-	1. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection. 4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with monosodium glutamate, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.'	12 September 2032
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		For the quantification of monosodium glutamate in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of monosodium glutamate in feedingstuffs: — Ion exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)						
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(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

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

2b621ii	Monosodium glutamate	<i>Additive composition</i> Monosodium glutamate <i>Characterisation of the active substance</i> Monosodium glutamate produced by <i>Corynebacterium glutamicum</i> NITE BP-01681 Purity: ≥ 99 % Chemical formula: C₅H₈NaNO₄·H₂O CAS number: 6106-04-3 EINECS number: 205-538-1 <i>Analytical method</i> (*) For the identification of monosodium L-glutamate monohydrate in the feed additive: — Food Chemical Codex monographs: 'Monosodium L-glutamate' For the quantification of monosodium glutamate in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)	All animal species	-	-	-	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feed with a moisture content of 12 %: 25 mg/kg.' - 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 of active substance in complete feed referred to in point 3. - For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection.	12 September 2032
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		For the quantification of monosodium glutamate in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and visible or fluorescence detection (IEC-VIS/FLD) or — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)						
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(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