Official Journal
of the European Union

EN
L series

2025/2505

12.12.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2505

of 11 December 2025

concerning the authorisation of guanidinoacetic acid and a preparation of guanidinoacetic acid as feed additives for weaned piglets and pigs for fattening in water for drinking and for turkeys for fattening and reared for breeding in feed and water for drinking (holder of authorisation: Alzchem Trostberg GmbH), and amending Implementing Regulation (EU) 2023/2628

(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) Guanidinoacetic acid and a preparation of guanidinoacetic acid ('the additives') were authorised as feed additives for use in feed for chickens for fattening, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) 2016/1768 ([2]).

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003, two applications were submitted for the authorisation of new uses of the additives. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The first application originally concerned the authorisation of both additives for all animal species for use in feed and in water for drinking, requesting the additives to be classified in the additive category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.

(5) On 6 May 2022, the applicant withdrew the first application for the authorisation of the additives for all animal species other than growing pigs and growing avian species. Additionally, on 23 January 2023, the applicant withdrew that application for all remaining species other than chickens for fattening for use in water, chickens reared for breeding/laying for use in feed and water, and weaned piglets and pigs for fattening for use in water.

(6) Commission Implementing Regulation (EU) 2023/2628 ([3]) authorised the additives for chickens reared for breeding and chickens reared for laying in feed and in water for drinking, and for chickens for fattening in water for drinking. The first application therefore only still concerns the use of the additives in water for drinking for weaned piglets and pigs for fattening.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

([2]) Commission Implementing Regulation (EU) 2016/1768 of 4 October 2016 concerning the authorisation of guanidinoacetic acid and a preparation of guanidinoacetic acid as feed additives for chickens for fattening, weaned piglets and pigs for fattening (holder of authorisation: Alzchem Trostberg GmbH) and repealing Commission Regulation (EC) No 904/2009 (OJ L 270, 5.10.2016, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2016/1768/oj).

([3]) Commission Implementing Regulation (EU) 2023/2628 of 27 November 2023 concerning the authorisation of guanidinoacetic acid and a preparation of guanidinoacetic acid as feed additives for chickens reared for breeding and chickens reared for laying in feed and in water for drinking, and chickens for fattening in water for drinking (holder of authorisation: Alzchem Trostberg GmbH), and correcting and amending Implementing Regulation (EU) 2016/1768 (OJ L, 2023/2628, 28.11.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2628/oj).

(7) The European Food Safety Authority ('the Authority') had concluded in its opinion of 28 September 2022 ([4]) that, under the proposed conditions of use, the additives are safe at 1 200 mg guanidinoacetic acid/kg complete feed or 600 mg guanidinoacetic acid/l water for piglets and pigs for fattening, consumers and the environment. The Authority further concluded that the additives are not toxic by inhalation, not irritant to skin and eyes and not dermal sensitisers. The Authority further stated that the proposed maximum safe levels of the additives were derived under the assumption that the feed contains sufficient amounts of methyl donors (other than methionine, e.g. choline, betaine and folic acid) and vitamin B12.

(8) The Authority also concluded in its opinions of 28 September 2022 and of 18 March 2025 ([5]) that the use of the additives in water for drinking has the potential to be efficacious in improving the zootechnical performance of weaned piglets and pigs for fattening under the proposed conditions of use.

(9) In its opinions on guanidinoacetic acid adopted on 27 January 2016 ([6]) and 28 September 2022, the Authority stated that the additives should not be considered as belonging to the functional group 'amino acids, their salts and analogues', because guanidinoacetic acid is exclusively converted to creatine and cannot be converted back to an amino acid, while the functional group 'amino acids, their salts and analogues' comprises substances which finally enter the metabolism of the body and as such take part in the protein synthesis pathways.

(10) The Authority did not consider in its opinion of 28 September 2022 that there is a need for specific requirements of post-market monitoring.

(11) The second application concerns the authorisation of the additives for turkeys for fattening and reared for breeding, specifically of guanidinoacetic acid in feed and water for drinking and of the preparation of guanidinoacetic acid in feed, requesting those additives to be classified in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives'.

(12) The Authority concluded in its opinion of 18 March 2025 ([7]) that the additives are safe for turkeys for fattening and reared for breeding, consumers and the environment at 1 200 mg guanidinoacetic acid/kg complete feed or 600 mg guanidinoacetic acid/l water, under the assumption that the feed contains sufficient amounts of methyl donors (other than methionine, e.g. choline, betaine and folic acid) and vitamin B12. It also reiterated its conclusion in previous assessments that the additives are not toxic by inhalation, not irritant to skin and eyes and not dermal sensitisers. The Authority further concluded that the additives have the potential to be efficacious in turkeys for fattening and turkeys reared for breeding at a minimum use level of 600 mg guanidinoacetic acid/kg complete feed or 300 mg guanidinoacetic acid/l water. It did not consider that there is a need for specific requirements of post-market monitoring.

(13) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additives and verified by the Authority in its opinion of 27 January 2016 are valid and applicable for both applications. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ([8]) an evaluation report of the Reference Laboratory was therefore not required.

([4]) *EFSA Journal* 2022; 20(5):7269, https://doi.org/10.2903/j.efsa.2022.7269.
([5]) *EFSA Journal* 2025; 23:e9350, https://doi.org/10.2903/j.efsa.2025.9350.
([6]) *EFSA Journal* 2016; 14(2):4394, https://doi.org/10.2903/j.efsa.2016.4394.
([7]) *EFSA Journal* 2025; 23:e9349, https://doi.org/10.2903/j.efsa.2025.9349.
([8]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

(14) In view of the above, the Commission considers that the additives satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of the additives should be authorised. It is appropriate, as regards the application for the authorisation of the additives for weaned piglets and pigs for fattening, to authorise the additives in the category 'zootechnical additives' and the functional group 'other zootechnical additives', taking into account the considerations from the Authority in relation to the effects of those additives on the zootechnical performance in piglets and pigs for fattening and the fact that they do not correspond to the type of products included in the functional group 'amino acids, their salts and analogues'. Furthermore, due to the authorisation of guanidinoacetic acid and of the preparation of guanidinoacetic acid for use both in feed and in water for drinking, it is appropriate to provide that the simultaneous use of the additives in feed and in water for drinking is not permitted, in order to avoid any risk of exceeding the safe levels of use for the target animals.

(15) In addition, considering that according to the Authority's opinions of 27 January 2016, 28 September 2022 and 18 March 2025 the safe and efficacious concentrations of the additives are primarily established in feed and then extrapolated to water for drinking, and that the water intake in pigs and poultry can vary from 2 to 3 times that of feed intake (in dry matter) ([9]), it is appropriate to ensure that the amount of guanidinoacetic acid administered via water for drinking remains within the range authorised in feed based on the actual intake of water for drinking relative to feed by the animals.

(16) Implementing Regulation (EU) 2023/2628 should therefore be amended accordingly.

(17) 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 substance and the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2023/2628

In Annex I to Implementing Regulation (EU) 2023/2628 in the column 'Other provisions' in each of the four tables the following point is added:

'6. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of guanidinoacetic acid administered via water for drinking is not higher than what it would be if fed at the maximum content of 1 200 mg/kg complete feed.'

([9]) Guidance on the identity, characterisation and conditions of use of feed additives, *EFSA Journal* 2017; 15(10):5023, https://doi.org/10.2903/j.efsa.2017.5023.

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.

Done at Brussels, 11 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Name of the 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 guanidinoacetic acid/l of water for drinking			
Category: Zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d372	Alzchem Trostberg GmbH	Guanidinoacetic acid	*Additive composition* Guanidinoacetic acid 98 % on dry matter basis. Solid form *Characterisation of the active substance* Guanidinoacetic acid produced by chemical synthesis Chemical formula: $C_3H_7N_3O_2$ CAS number: 352-97-6 Purity: 98 % Impurities: — maximum cyanamide content 0,03 %; — maximum dicyandiamide content 0,5 %. *Analytical method* (1) For the determination of guanidinoacetic acid in water for drinking: ion chromatography coupled with ultraviolet detection (IC-UV).	Weaned piglets Pigs for fattening	-	200	600	1. The moisture content shall be indicated on the labelling of the additive. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive, the storage conditions and the stability in water for drinking shall be indicated. 4. When using the additive, attention shall be paid to the supply with vitamin B_{12} and methyl donors other than methionine in the diet of the animal. 5. Simultaneous use of this additive in water for drinking and in feed is not permitted. 6. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of guanidinoacetic acid administered via water for drinking is not lower than what it would be if fed at the minimum content of 600 mg/kg complete feed, nor higher than what it would be if fed at the maximum content of 1 200 mg/kg complete feed.	1 January 2036

(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	Name of the holder of authorisation	Name of the 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 guanidinoacetic acid/l of water for drinking			
Category: Zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d372i	Alzchem Trostberg GmbH	Guanidinoacetic acid	*Additive composition* Preparation containing a minimum of 96 % of guanidinoacetic acid. Solid form *Characterisation of the active substance* Guanidinoacetic acid produced by chemical synthesis Chemical formula: $C_3H_7N_3O_2$ CAS number: 352-97-6 Purity: 98 % Impurities: — maximum cyanamide content 0,03 %; — maximum dicyandiamide content 0,5 %. *Analytical method* (1) For the determination of guanidinoacetic acid in water for drinking: ion chromatography coupled with ultraviolet detection (IC-UV).	Weaned piglets Pigs for fattening	-	200	600	1. The moisture content shall be indicated on the labelling of the additive. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive, the storage conditions and the stability in water for drinking shall be indicated. 4. When using the additive, attention shall be paid to the supply with vitamin B_{12} and methyl donors other than methionine in the diet of the animal. 5. Simultaneous use of this additive in water for drinking and in feed is not permitted. 6. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of guanidinoacetic acid administered via water for drinking is not lower than what it would be if fed at the minimum content of 600 mg/kg complete feed, nor higher than what it would be if fed at the maximum content of 1 200 mg/kg complete feed.	1 January 2036

(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	Name of the holder of authorisation	Name of the additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg guanidinoacetic acid/kg of complete feed with a moisture content of 12 %		mg guanidinoacetic acid/l of water for drinking			
Category: Zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)											
4d372	Alzchem Trostberg GmbH	Guanidinoacetic acid	*Additive composition* Guanidinoacetic acid 98 % on a dry matter basis. Solid form *Characterisation of the active substance* Guanidinoacetic acid produced by chemical synthesis Chemical formula: $C_3H_7N_3O_2$ CAS number: 352-97-6 Purity: 98 % Impurities: — maximum cyanamide content 0,03 %; — maximum dicyandiamide content 0,5 %. *Analytical method* (1) For the determination of guanidinoacetic acid in the feed additive, premixtures, compound feed and water for drinking: ion chromatography coupled with ultraviolet detection (IC-UV).	Turkeys for fattening Turkeys reared for breeding	-	600	1 200	300	600	1. The moisture content shall be indicated on the labelling of the additive. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. When using the additive, attention shall be paid to the supply with vitamin B_{12} and methyl donors other than methionine in the diet of the animal.	1 January 2036

Identification number of the additive	Name of the holder of authorisation	Name of the additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg guanidinoacetic acid/kg of complete feed with a moisture content of 12 %		mg guanidinoacetic acid/l of water for drinking			
										5. Simultaneous use of this additive in water for drinking and in feed is not permitted. 6. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of guanidinoacetic acid administered via water for drinking is not higher than what it would be if fed at the maximum content of 1 200 mg/kg complete feed.	

([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.

ELI: http://data.europa.eu/eli/reg_impl/2025/2505/oj

Identification number of the additive	Name of the holder of authorisation	Name of the 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 guanidinoacetic acid/kg of complete feed with a moisture content of 12 %			
Category: Zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d372i	Alzchem Trostberg GmbH	Guanidinoacetic acid	*Additive composition* Preparation containing a minimum of 96 % of guanidinoacetic acid. Solid form *Characterisation of the active substance* Guanidinoacetic acid produced by chemical synthesis Chemical formula: $C_3H_7N_3O_2$ CAS number: 352-97-6 Purity: 98 % Impurities: — maximum cyanamide content 0,03 %; — maximum dicyandiamide content 0,5 %. *Analytical method* (1) For the determination of guanidinoacetic acid in the feed additive, premixtures and compound feed: ion chromatography coupled with ultraviolet detection (IC-UV).	Turkeys for fattening Turkeys reared for breeding	-	600	1 200	1. The moisture content shall be indicated on the labelling of the additive. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 3. When using the additive, attention shall be paid to the supply with vitamin B_{12} and methyl donors other than methionine in the diet of the animal.	1 January 2036

(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.