



2023/2628

28.11.2023

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

(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) The additive guanidinoacetic acid was authorised as a substance and as a preparation 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, an application was submitted for the authorisation of new uses of guanidinoacetic acid and a preparation of guanidinoacetic acid. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) That application concerns the authorisation of guanidinoacetic acid and a preparation of guanidinoacetic acid as feed additives for all animal species for use in feed and in water for drinking, requesting those additives to be classified in the category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 September 2022 ⁽³⁾ that, under the proposed conditions of use in feed and in water for drinking, guanidinoacetic acid and a preparation of guanidinoacetic acid are safe for chickens for fattening, chickens reared for breeding, chickens reared for laying, piglets and pigs for fattening for use in feed and in water for drinking, and safe for consumers and the environment. The Authority further concluded that guanidinoacetic acid is not toxic by inhalation, that it is not an irritant to skin and eyes and that it is not a dermal sensitiser. The Authority recommended to consider that the proposed maximum safe levels of the additives are based on the assumption that the feed contains sufficient methyl donors (other than methionine, e.g. choline, betaine and folic acid) and vitamin B₁₂.
- (6) The Authority also concluded that the additives have the potential to be efficacious for chickens reared for laying and for breeding, chickens for fattening, weaned piglets and pigs for fattening. This efficacy is related to an improvement of performance parameters in those animal species. In its opinions on guanidinoacetic acid adopted on 27 January 2016 ⁽⁴⁾ and 28 September 2022, the Authority stated that this additive should not be considered as belonging to the functional group 'amino acids, their salts and analogues', because guanidinoacetic acid is exclusively converted

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2016/1768 of 4 October 2016 concerning the authorisation of guanidinoacetic acid as a feed additive for chickens for fattening, weaned piglets and pigs for fattening and repealing Commission Regulation (EC) No 904/2009 (OJ L 270, 5.10.2016, p. 4).

⁽³⁾ EFSA Journal 2022;20(5):7269.

⁽⁴⁾ EFSA Journal 2016;14(2):4394.

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. The Authority further concluded that to support a new nutritional effect of the additives concerned, relevant evidence of their efficacy in pigs and poultry should be provided. The Authority did 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 and in water submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (7) Guanidinoacetic acid and the preparation of guanidinoacetic acid should therefore be re-allocated to 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 the additives on animal's zootechnical performance and the fact that they do not correspond to the type of products included in the functional group 'amino acids, their salts and analogues'.
- (8) Pursuant to Commission Regulation (EC) No 429/2008 ⁽⁵⁾ and the Authority's guidance on the assessment of the efficacy of feed additives ⁽⁶⁾, a minimum of three studies should be provided to demonstrate efficacy for the relevant target species and categories of animals as regards zootechnical additives affecting animal production or performance. Accordingly, additional studies should be provided by the applicant with regard to the use of guanidinoacetic acid and the preparation of guanidinoacetic acid for weaned piglets and pigs for fattening.
- (9) Implementing Regulation (EU) 2016/1768 provides that guanidinoacetic acid is allowed to be placed on the market and used as an additive consisting of a preparation, but the composition of such preparation has erroneously not been specified in the terms of the authorisation. A more accurate description of guanidinoacetic acid authorised both as a substance and as a preparation by Implementing Regulation (EU) 2016/1768 should be provided for, by specifying the composition of the additive authorised as a preparation. A different identification number should also be assigned to distinguish between the two forms of additive.
- (10) Both the re-allocation of the additives to the functional group 'other zootechnical additives', including the mention of the holder of the authorisation, and the specification of the composition of the preparation of guanidinoacetic acid should be reflected in the authorisation granted by Implementing Regulation (EU) 2016/1768, which should therefore be corrected accordingly.
- (11) In addition, the authorisation granted by Implementing Regulation (EU) 2016/1768 should provide for specific labelling requirements concerning the storage and stability conditions of the additives and premixtures concerned. That authorisation should also no longer refer to users' safety procedures and measures, based on the conclusions of the Authority's opinion of 28 September 2022. 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. Implementing Regulation (EU) 2016/1768 should therefore be amended accordingly.
- (12) The assessment of guanidinoacetic acid and of the preparation of guanidinoacetic acid shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied as regards their use for chickens for fattening, chickens reared for laying and chickens reared for breeding. Accordingly, the use of those additives should be authorised for use in feed and in water for drinking. As regards the use in feed, the authorisation granted by this Regulation should only concern chickens reared for breeding and chickens reared for laying.

⁽⁵⁾ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

⁽⁶⁾ EFSA Journal 2018;16(5):5274.

- (13) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the additives authorised by Implementing Regulation (EU) 2016/1768, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from those modifications. In particular, the re-allocation of the additives to the category 'zootechnical additives' results in the granting of the related authorisation to a specific holder. The transitional period should therefore allow interested parties to submit an application for authorisation of the additives concerned belonging to the category 'zootechnical additives', and it should take account of the time needed to process such an application in accordance with Regulation (EC) No 1831/2003. However, the transitional period should not exceed the expiry date of the authorisation granted by Implementing Regulation (EU) 2016/1768.
- (14) 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 Annex I, 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

Correction and amendment to Implementing Regulation (EU) 2016/1768

1. The title of Implementing Regulation (EU) 2016/1768 is replaced by the following:

'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'.

2. Article 1 of Implementing Regulation (EU) 2016/1768 is replaced by the following:

'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.'

3. The Annex to Implementing Regulation (EU) 2016/1768 is replaced by Annex II to this Regulation.

Article 3

Transitional measures

The substance and the preparation specified in Annex II, for use in feed for chickens for fattening, weaned piglets and pigs for fattening, and feed containing them, may continue to be placed on the market and used until 25 October 2026 in accordance with the rules applicable before 18 December 2023.

*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, 27 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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	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: C₃H₇N₃O₂ 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 compound feed and water: ion chromatography coupled with ultraviolet detection (IC-UV).	Chickens reared for laying and 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 B₁₂ 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.	18 December 2033
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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	Name of the holder of authorisation	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)

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 compound feed and water: ion chromatography coupled with ultraviolet detection (IC-UV).	Chickens reared for laying and 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 B₁₂ 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.	18 December 2033
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ANNEX II

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 guanidinoacetic acid/kg of complete feed with a moisture content of 12 %			

Category: Zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)

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				Weaned piglets		600	1 200		
				Pigs for fattening		600	1 200		

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				Pigs for fattening		600	1 200		

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