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 (Text with EEA relevance)

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

(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) Guanidinoacetic acid was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 904/2009[(2)].

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of guanidinoacetic acid as a feed additive. That 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 as a feed additive for chickens for fattening, chickens reared for breeding and pigs to be classified in the additive category ‘nutritional additives’.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 27 January 2016[(3)] that, under the proposed conditions of use, guanidinoacetic acid does not have an adverse effect on animal health, consumer health or the environment and that it is considered to be a source of creatine and may therefore substitute dietary creatine. The Authority recommended protective measures are taken to avoid inhalation by the users. The Authority stated that maximum safe levels were derived under the assumption that the feed contains sufficient amounts of methyl donors. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the substance concerned 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) As a new authorisation is granted in accordance with Regulation (EC) No 1831/2003, Regulation (EC) No 904/2009 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for the disposal of existing stocks of the additive, pre-mixtures and compound feed containing it, as authorised by Regulation (EC) No 904/2009.

(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

The substance specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 904/2009 is repealed.

Article 3

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 25 April 2017 in accordance with the rules applicable before 25 October 2016 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substance referred to in paragraph 1 may be placed on the market until 25 October 2017 in accordance with the rules applicable before 25 October 2016 and used until the existing stocks are exhausted.

Article 4

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1768. (See end of Document for details)*

Done at Brussels, 4 October 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1768. (See end of Document for details)*

ANNEX

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 of nutritional additives. Functional group: amino acids, their salts and analogues									
3c372	—	Guanidinoacetic acid	*Additive composition* Powder with a minimum content of 98 % guanidinoacetic acid (on a dry matter basis). *Characterisation of the active substance* Guanidinoacetic acid produced by chemical synthesis Chemical formula: $C_3H_7N_3O_2$ CAS number: 352-97-6 Impurities: — maximum cyanamide content 0,03 %; — maximum dicyandiamide	Chickens for fattening, weaned piglets and pigs for fattening		600	1 200	1. In the feeding instructions and on the labelling of the additive, a withdrawal period of 5 days shall be indicated. 2. Guanidinoacetic acid may be placed on the market and used as an additive consisting of a preparation. 3. When using the additive, attention shall be paid	25 October 2026

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports