

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1682

of 29 June 2023

concerning the renewal of the authorisation of dimethylglycine sodium salt as a feed additive for chickens for fattening (holder of the authorisation: Taminco BV) and repealing Implementing Regulation (EU) No 371/2011

(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 and renewing such authorisation.
- (2) Dimethylglycine sodium salt was authorised for a period of 10 years as a feed additive for chickens for fattening by Commission Implementing Regulation (EU) No 371/2011 (²).
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of dimethylglycine sodium salt as a feed additive for chickens for fattening, requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives: (improvement of zootechnical parameters)'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 (³) that the applicant had provided evidence that the additive remains safe for chickens for fattening, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is not a skin irritant but may be an eye irritant and skin sensitiser.

(¹) OJ L 268, 18.10.2003, p. 29.

(²) Commission Implementing Regulation (EU) No 371/2011 of 15 April 2011 concerning the authorisation of dimethylglycine sodium salt as a feed additive for chickens for fattening (OJ L 102, 16.4.2011, p. 6).

(³) EFSA Journal 2021;19(5):6621

(5) The Annex to Implementing Regulation (EU) No 371/2011 erroneously provides for the description of the functional group 'zootechnical additives (improvement of zootechnical parameters)'. The opinion of the European Food Safety Authority ('the Authority') of 7 December 2010 ⁽⁴⁾ stated that the additive has the potential to increase performance in chickens for fattening. The term 'zootechnical' is too generic and may encompass different functions, while not expressing the specific effects of the additive. Therefore, in order to be in line with the opinion of the Authority, the functional group of the feed additive should refer to the improvement of performance parameters. In addition, the Authority concluded in its opinion of 7 December 2020 ⁽⁵⁾ that the additive is efficacious at a level of 1 000 mg/kg, consequently, a minimum level should be established.

(6) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁶⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are applicable for the current application.

(7) The assessment of dimethylglycine sodium salt shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(8) As a consequence of the renewal of the authorisation of dimethylglycine sodium salt as a feed additive, Implementing Regulation (EU) No 371/2011 should be repealed.

(9) Considering that the functional group should appear on the label of the feed additive, of the premixtures and compound feed containing it, it is necessary to provide for a transitional period allowing feed business operators to make the necessary adaptations to the labels.

(10) 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

Renewal of the authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives: (improvement of performance parameters)', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 371/2011

Implementing Regulation (EU) No 371/2011 is repealed.

⁽⁴⁾ EFSA Journal (2011); 9(1):1950

⁽⁵⁾ EFSA Journal 2021;19(5):6621

⁽⁶⁾ 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).

*Article 3***Transitional measures**

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 24 March 2024 in accordance with the rules applicable before 24 September 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance specified in the Annex, which are produced and labelled before 24 September 2024 in accordance with the rules applicable before 24 September 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for chickens for fattening.

*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, 29 June 2023.

For the Commission

The President

Ursula VON DER LEYEN

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 of additive/kg of complete feedingstuff with a moisture content of 12%			

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

4d4	Taminco BV.	Dimethylglycine sodium salt	<p><i>Additive composition</i> Dimethylglycine sodium salt with a purity of at least 97 % Solid form</p> <p><i>Characterisation of the active substance</i> Sodium N,N-dimethylglycine produced by chemical synthesis.</p> <p>Dimethylaminoethanol (DMAE)≤ 0.1 % Chemical formula: C₄H₈NO₂Na CAS number: 18319-88-5 EINECS number: 242-206-5</p> <p><i>Analytical method (¹)</i> For the determination of dimethylglycine sodium salt in the feed additive and premixtures: liquid chromatography (HPLC) with diode array detection (DAD), detection at 193 nm. For the determination of the active substance in compound feed: gas chromatography (GC) using pre-column derivatisation and flame ionisation detection (FID).</p>	Chickens for fattening	—	1 000	1 000	For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing eye and skin protective equipment.	24 September 2033
-----	-------------	-----------------------------	--	------------------------	---	-------	-------	--	-------------------

(¹) 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>.