COMMISSION IMPLEMENTING REGULATION (EU) 2023/1708

of 7 September 2023

concerning the renewal of the authorisation of urea as a feed additive for ruminants with a functional rumen and repealing Implementing Regulation (EU) No 839/2012

(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) Urea was authorised for a period of 10 years as a feed additive for ruminants with a functional rumen by Commission Implementing Regulation (EU) No 839/2012 ([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 urea as a feed additive for ruminants with a functional rumen, requesting the additive to be classified in the additive category 'nutritional additives' and in the functional group 'urea and its derivatives'. 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 11 January 2023 ([3]) that the applicant provided evidence that the additive remains safe for the target species, the consumers and the environment under the existing conditions of authorisation. In the absence of new information providing evidence for the safety of the additive for the user, the Authority could not conclude on the users' safety. The Authority also indicated that the conclusion made previously on the efficacy remains valid. It did not consider that there is a need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of urea as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([4]), an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers 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.

(7) As a consequence of the renewal of the authorisation of urea as a feed additive, Implementing Regulation (EU) No 839/2012 should be repealed.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) No 839/2012 of 18 September 2012 concerning the authorisation of urea as a feed additive for ruminants (OJ L 252, 19.9.2012, p. 11).

([3]) *EFSA Journal* 2023;21(2):7821.

([4]) 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).

(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

Renewal of authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'urea and its derivatives', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 839/2012

Implementing Regulation (EU) No 839/2012 is repealed.

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, 7 September 2023.

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 of the additive/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: Urea and its derivatives								
3d1	Urea	*Additive composition* Urea content: minimum 97 % Nitrogen content: 46 % Solid form *Characterisation of the active substance* Diaminomethanone, CAS number 57-13-6, chemical formula: $(NH_2)_2CO$ *Analytical method* (1) For the determination of the total nitrogen in the additive: Titrimetry (EN 15478) For the determination of the biuret contribution to the total nitrogen in the additive: Spectrophotometry (EN 15479) For the determination of urea in premixtures, compound feed and feed materials: Spectrophotometry (Annex III.D to Regulation (EC) No 152/2009)	Ruminants with a functional rumen			8 800	1. In the directions for use of the additive and feed containing it, the following shall be indicated: 'Urea shall only be fed to animals with a functional rumen. Feeding urea to the maximum level dose should be done gradually. The maximum content of urea should be fed only as part of diets rich in easily digestible carbohydrates and low in soluble nitrogen. A maximum 30 % of total nitrogen in the daily ration should come from urea-N.' 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 skin, eye and breathing protective equipment.	28 September 2033

(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.