Commission Implementing Regulation (EU) No 839/2012 of 18 September 2012 concerning the authorisation of urea as a feed additive for ruminants (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 839/2012

of 18 September 2012

concerning the authorisation of urea as a feed additive for ruminants

(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. Article 10 of that Regulation provides for the re-evaluation of products authorised pursuant to Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[(2)].

(2) Urea was authorised without a time limit by Directive 82/471/EEC. That product was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of urea as a feed additive for ruminants, requesting that additive to be classified in the additive category ‘nutritional additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 7 March 2012[(3)] that, under the proposed conditions of use, urea does not have an adverse effect on animal health, human health or the environment, and that it provides non-protein nitrogen for microbial protein synthesis in the rumen. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of urea 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 839/2012. (See end of Document for details)*

(6) Since modifications to the conditions of authorisation of urea are introduced and as there are no direct immediate effects on safety, a reasonable period should be allowed to elapse before authorisation in order to allow the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, it is appropriate to allow a transitional period for the disposal of existing stocks of urea, as authorised by Directive 82/471/EEC, and of feed containing urea.

(7) It is disproportionately complex for operators to adapt repeatedly and from one day to the other labels of feed containing different additives which have been successively authorised according to the procedure laid down in Article 10(2) of Regulation (EC) No 1831/2003 and for which new labelling rules are to be complied with. It is therefore appropriate to reduce the administrative burden on the operators by providing a period of time allowing a smooth conversion of labelling.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘urea and its derivatives’ is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Labelling requirements

Feed containing urea shall be labelled in accordance with this Regulation at the latest by 19 May 2013.

However, feed containing urea which has been labelled in accordance with Directive 82/471/EEC before 19 May 2013 may continue to be placed on the market until stocks are exhausted.

Article 3

Transitional measures

Existing stocks of urea and of feed containing urea at the date of entry into force of this Regulation may continue to be placed on the market and used under the conditions of Directive 82/471/EEC until they are exhausted.

Article 4

Entry into force

This Regulation shall enter into force on 19 November 2012.

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) No 839/2012. (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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: Urea and its derivatives									
3d1	—	Urea	*Additives with a functional rumen*	*Ruminants – with a rumen*			8 800	The directions for use of the feed additive and feed containing urea shall include the following: 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	19 November 2022

Composition: Urea content: minimum 97 % Nitrogen content: 46 %

Characterisation of the active substance: Diaminomethanone, [X1CAS number 57-13-6], chemical formula: $(NH_2)_2CO$

Analytical methods[a]: For the determination of the total nitrogen in the additive: Titrimetry (method 2.3.3 in Annex IV

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx