Commission Implementing Regulation (EU) No 842/2012 of 18 September 2012 concerning the authorisation of a preparation of lanthanum carbonate octahydrate as a feed additive for dogs (holder of authorisation Bayer Animal Health GmbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 842/2012

of 18 September 2012

concerning the authorisation of a preparation of lanthanum carbonate octahydrate as a feed additive for dogs (holder of authorisation Bayer Animal Health GmbH)

(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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation of lanthanum carbonate octahydrate, CAS number 6487-39-4. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation lanthanum carbonate octahydrate CAS number 6487-39-4 as a feed additive for dogs, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that preparation was authorised for 10 years for cats by Commission Regulation (EC) No 163/2008[(2)].

(5) New data were submitted in support of the application for authorisation of lanthanum carbonate octahydrate, CAS number 6487-39-4, for dogs. The European Food Safety Authority (‘the Authority’) concluded in its opinion of 6 March 2012 that, under the proposed conditions of use, lanthanum carbonate octahydrate does not have an adverse effect on the target species[(3)]. It further concluded that lanthanum carbonate octahydrate has the potential to reduce the phosphorus bioavailability in adult dogs. It could not, however, comment on the long-term effects. 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 842/2012. (See end of Document for details)*

(6) The assessment of lanthanum carbonate octahydrate, CAS number 6487-39-4, 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 preparation should be authorised, as specified in the Annex to this Regulation. It is appropriate to provide for post-market monitoring as regards long-term adverse effects.

(7) 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

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

Article 2

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, 18 September 2012.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 842/2012. (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 feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (decrease in phosphorus excretion via urine)									
4d1	Bayer Animal Health GmbH	Lanthanum carbonate octahydrate	*Additive composition* Preparation of lanthanum carbonate octahydrate. At least 85 % lanthanum carbonate octahydrate as active substance *Characterisation of the active substance* Lanthanum carbonate octahydrate $La_2(CO_3)_3 \cdot 8H_2O$ CAS number 6487-39-4 *Analytical method*[a] Quantification of	Dogs	—	1 500	7 500	Post-market monitoring on chronic adverse effects is required. In the directions for use of the additive: — for adult dogs — recommended dose of inclusion in moist feed with 20-25 % dry matter content: 340 to 2 100 mg per kg	9 October 2022

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

b OJ L 54, 26.2.2009, p. 1.