



EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisations of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening and a preparation of montmorillonite-illite for all animal species as feed additives

(Text with EEA relevance)

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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 nutrition¹, 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 applications were submitted for the authorisations of a preparation of dolomite-magnesite and a preparation of montmorillonite-illite. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) Those applications concern the authorisations of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned piglets and pig for fattening and a preparation of montmorillonite-illite as feed additives for all animal species to be classified in the additive category “technological additives”.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 December 2015² that the preparation of dolomite-magnesite does not have an adverse effect on animal health on the environment or human health. The Authority has also concluded that it is efficacious as an anticaking agent. 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.
- (5) Due to the physiological similarity of the dairy cows with all ruminants for dairy production, it is appropriate to extend the use of this additive to other ruminants for dairy production.
- (6) The Authority concluded in its opinion of 10 September 2015³ that the preparation of montmorillonite-illite does not have an adverse effect on animal health, on the environment or human health. The Authority has also concluded that it is efficacious

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2016;14(1):4341

³ EFSA Journal 2015;13(9):4237

as an anticaking agent and as binder. 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.

- (7) The assessment of the preparation of dolomite-magnesite and of the preparation of montmorillonite-illite shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annexes to this Regulation.
- (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

The preparation specified in the Annex I, belonging to the additive category 'technological additives' and to the functional group 'anticaking agents, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

The preparation specified in the Annex II, belonging to the additive category 'technological additives' and to the functional groups 'anticaking agents' and 'binders', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 3

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,

For the Commission
The President
Jean-Claude JUNCKER