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**[...]**(2026) **XXX** draft

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

**of **XXX****

**concerning the authorisation of clinoptilolite of volcanic origin as a feed additive for  
poultry for fattening, poultry reared for laying or reproduction, ornamental birds,  
piglets and pigs for fattening**

(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 nutrition<sup>1</sup>, 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of clinoptilolite of volcanic origin. 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 clinoptilolite of volcanic origin as a feed additive for all terrestrial animal species, requesting that additive to be classified in the category ‘technological additives’ and in the functional groups ‘binders and anticaking agents’.
- (4) The European Food Safety Authority (‘the Authority’) in its opinion of 18 November 2025<sup>2</sup> concluded that clinoptilolite of volcanic origin at the maximum safe level of 20,000 mg/kg complete feed is safe for all poultry for fattening, poultry reared for laying or reproduction, ornamental birds, suckling and weaned piglets and pigs for fattening. No conclusion can be drawn for other terrestrial species/categories. It also concluded that the additive is safe for the consumer and the environment at the proposed conditions of use. Regarding user safety, the Authority concluded that the additive is not irritant to the skin or eyes but should be considered a dermal and skin sensitiser. Exposure by dermal and inhalation routes is considered a risk and should be minimised. It further concluded that clinoptilolite of volcanic origin is efficacious as a pellet binder and anticaking agent in feed for terrestrial animal species, while noting that the efficacy as pellet binder has been shown at an inclusion level of 20,000–30,000 mg/kg complete feed, levels higher than the ones for which the safety has been supported. The Authority also verified the report on the method of analysis of the feed

<sup>1</sup> OJ L 268, 18.10.2003, p. 29. ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

<sup>2</sup> EFSA Journal. 2025;23:e9780. <https://doi.org/10.2903/j.efsa.2025.9780>.

Feltkode ændret

additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) Following EFSA opinion, on 16.02.2026, the applicant formally requested the partial withdrawal of the above-mentioned application as regards the authorisation of the additive as anticaking agent for all terrestrial animals other than all poultry for fattening, poultry reared for laying or reproduction, ornamental birds, piglets (suckling and weaned), and pigs for fattening and the authorisation of the additive under functional group 'binders'.
- (6) In view of the above, the Commission considers that clinoptilolite of volcanic origin satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised for poultry for fattening, poultry reared for laying or reproduction, ornamental birds, piglets and pigs for fattening. 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) 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*  
**Authorisation**

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

*Article 2*  
**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,

*For the Commission*  
*The President*  
Ursula VON DER LEYEN