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

**of **XXX****

**concerning the renewal of the authorisation of clinoptilolite of sedimentary origin as a  
feed additive for all animal species and repealing Implementing Regulation (EU) No  
651/2013**

(Text with EEA relevance)

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

of **XXX**

**concerning the renewal of the authorisation of clinoptilolite of sedimentary origin as a feed additive for all animal species and repealing Implementing Regulation (EU) No 651/2013**

(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<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 and renewing such an authorisation.
- (2) The substance clinoptilolite of sedimentary origin was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 651/2013<sup>2</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of clinoptilolite of sedimentary origin as a feed additive for all animal species, requesting the additive to be classified in the additive category ‘technological additives’ and in the functional groups ‘binders’ and ‘anticaking agents’. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 19 March 2025<sup>3</sup> that the additive clinoptilolite of sedimentary origin remains safe for all animal species, consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is not a skin nor an eye irritant but should be considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. The Authority also indicated that there is no need for assessing the efficacy of the additive, as the application for renewal of its authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation which would have an impact on the efficacy of the additive.

<sup>1</sup> OJ L 268, 18.10.2003, p. 29, ELI: <https://eur-lex.europa.eu/eli/reg/2003/1831/oj>.

<sup>2</sup> Commission Implementing Regulation (EU) No 651/2013 of 9 July 2013 concerning the authorisation of clinoptilolite of sedimentary origin as a feed additive for all animal species and amending Regulation (EC) No 1810/2005 (OJ L 189, 10.7.2013, pp. 1, ELI: [http://data.europa.eu/eli/reg\\_impl/2013/651/oj](http://data.europa.eu/eli/reg_impl/2013/651/oj)).

<sup>3</sup> EFSA Journal. 2025;23:e9364. <https://doi.org/10.2903/j.efsa.2025.9364>.

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(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 the clinoptilolite of sedimentary origin 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<sup>4</sup>, an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the clinoptilolite of sedimentary origin satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(7) As a consequence of the renewal of the authorisation of clinoptilolite of sedimentary origin as a feed additive, Implementing Regulation (EU) No 651/2013 should be repealed.

(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 the authorisation**

The authorisation of the substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional groups 'binders' and 'anticaking agents', is renewed, subject to the conditions laid down in that Annex.

*Article 2*  
**Repeal**

Implementing Regulation (EU) No 651/2013 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.

<sup>4</sup> 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, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

Done at Brussels,

*For the Commission  
The President  
Ursula VON DER LEYEN*

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