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[...] (2025) **XXX** draft

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

of **XXX**

**concerning the authorisation of 4-hydroxy-2,5-dimethylfuran-3(2H)-one as a feed
additive for all animal species except cats and dogs**

(Text with EEA relevance)

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(Text with EEA relevance) **This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.**

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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of 4-hydroxy-2,5-dimethylfuran-3(2H)-one. 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 4-hydroxy-2,5-dimethylfuran-3(2H)-one, as a feed additive for all animal species except cats and dogs, requesting that additive to be classified in the category ‘sensory additives’ and in the functional group ‘flavouring compounds’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 24 June 2025² that, under the proposed conditions of use, 4-hydroxy-2,5-dimethylfuran-3(2H)-one, is safe for all animal species as well as for consumers and the environment. It also concluded that the additive is irritant to the skin, eyes and respiratory tract and is a dermal a respiratory sensitiser. Any exposure is considered a risk. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning

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

² EFSA Journal. 2025;23:e9538. <https://doi.org/10.2903/j.efsa.2025.9538>.

another application for the authorisation of the same additive and verified by the Authority in its opinion of 23 July 2012³ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁴, an evaluation report of the Reference Laboratory was therefore not required.

- (6) In view of the above, the Commission considers that 4-hydroxy-2,5-dimethylfuran-3(2H)-one, satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised for all animal species except cats and dogs. 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 Commission considers that safety reasons do not require the setting of maximum contents for 4-hydroxy-2,5-dimethylfuran-3(2H)-one. In order to allow better control, the recommended maximum content should be indicated on the label of the additive. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.
- (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 **Authorisation**

The substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, 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

³ EFSA Journal 2012;10(7):2786.

⁴ 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).]