



Brussels, **XXX**
SANTE/8474699/2024 CIS
(POOL/G5/2024/8474699/8474699-EN
CIS.docx)
[...](2025) **XXX** draft

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

of **XXX**

concerning the renewal of the authorisation of fumaric acid as a feed additive for all terrestrial animal species, repealing Implementing Regulation (EU) No 1078/2013 and amending Implementing Regulation (EU) 2017/56

(Text with EEA relevance)

EN

EN

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

of XXX

concerning the renewal of the authorisation of fumaric acid as a feed additive for all terrestrial animal species, repealing Implementing Regulation (EU) No 1078/2013 and amending Implementing Regulation (EU) 2017/56

(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 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 and renewing such authorisation.
- (2) Fumaric acid was authorised for a period of 10 years for all animal species as a feed additive in the functional group ‘preservatives’ by Commission Implementing Regulation (EU) No 1078/2013², and in the functional group ‘flavouring compounds’ by Commission Implementing Regulation (EU) 2017/56³.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of fumaric acid as a feed additive for all animal species, requesting that additive to be classified in the category ‘technological additives’, functional group ‘preservatives’ and in the category ‘sensory additives’, functional group ‘flavouring compounds’. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of fumaric acid in the category ‘nutritional additives’, functional group ‘acidity regulator’. Those applications were accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of that Regulation.

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

² Commission Implementing Regulation (EU) No 1078/2013 of 31 October 2013 concerning the authorisation of fumaric acid as a feed additive for all animal species (OJ L 292, 1.11.2013, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2013/1078/oj).

³ Commission Implementing Regulation (EU) 2017/56 of 14 December 2016 concerning the authorisation of lactic acid, 4-oxovaleric acid, succinic acid, fumaric acid, ethyl acetoacetate, ethyl lactate, butyl lactate, ethyl 4-oxovalerate, diethyl succinate, diethyl malonate, butyl-O-butyryllactate, hex-3-enyl lactate, hexyl lactate, butyro-1,4-lactone, decano-1,5-lactone, undecano-1,5-lactone, pentano-1,4-lactone, nonano-1,5-lactone, octano-1,5-lactone, heptano-1,4-lactone and hexano-1,4-lactone as feed additives for all animal species (OJ L 13, 17.1.2017, p. 129, ELI: http://data.europa.eu/eli/reg_impl/2017/56/oj).

formaterede: Dansk

formaterede: Dansk

formaterede: Dansk

Feltkode ændret

EN

EN

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 September 2024⁴ that fumaric acid remains safe under the authorised conditions of use for the terrestrial animals, consumers and the environment, while it could not conclude on the safety for the aquatic animals, noting that the data available on the safety of fumaric acid on aquatic animals is scarce. It also considered that the new use of the additive as an acidity regulator under the proposed conditions of use would not introduce risks, which are not already considered. The Authority also concluded that fumaric acid is irritant to skin, eyes and respiratory tract, and should be considered a skin and respiratory sensitiser. The Authority stated that there is no need for assessing the efficacy of fumaric acid for its use as a preservative and as a flavouring compound, as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation in this regard, while it was not in the position to conclude on its efficacy as an acidity regulator in feed.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment carried out regarding the methods of analysis of fumaric acid as a feed additive is valid and applicable for the current application. That previous assessment took place in the context of a new evaluation of the methods of analysis concerned performed by the Reference Laboratory, which is referred to in the Authority's opinions of 17 September 2024, in order to take account of scientific and technological developments and to ensure a better suitability of the methods of analysis for official controls.

(6) By letter of 21 November 2024, the applicant withdrew the application for the renewal of the authorisation as regards the use of fumaric acid for aquatic animals and the application for its use as an acidity regulator.

(7) In view of the above, the Commission considers that fumaric acid satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, as far as it concerns its use as a feed additive for terrestrial animals. 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.

(8) As a consequence of the renewal of the authorisation of fumaric acid as a feed additive for terrestrial animals, Implementing Regulation (EU) No 1078/2013 should be repealed and Implementing Regulation (EU) 2017/56 should be amended to maintain the authorisation of the additive only for the use for animal species which are not the subject of the renewal of the authorisation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ EFSA Journal,
<https://doi.org/10.2903/j.efsa.2024.9019>.

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’, functional group ‘preservatives’ and in the category ‘sensory additives’, functional group ‘flavouring compounds’, is renewed subject to the conditions laid down in that Annex.

Article 2
Repeal of Implementing Regulation (EU) No 1078/2013

Implementing Regulation (EU) No 1078/2013 is repealed.

Article 3
Amendment to Implementing Regulation (EU) 2017/56

In the fifth column of the entry 2b08025 of the Annex to Implementing Regulation (EU) 2017/56, the words “All animal species” are replaced by the words “Aquatic animal species”.

Article 4

Transitional measures

1. The feed additive fumaric acid, as authorised by Implementing Regulation No 1078/2013 and No 2017/56 and premixtures containing those additives, which are intended for terrestrial animal species, and which are produced and labelled before [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication], may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication], may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing terrestrial animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before [24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication], may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing terrestrial animals.

Article 5
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