

Brussels, XXX SANTE/6330008/2024 CIS (POOL/G5/2024/6330008/6330008-EN CIS.docx) [...](2025) XXX draft

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

of XXX

concerning the renewal of the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives for all terrestrial animal species and repealing Implementing Regulations (EU) No 1222/2013 and (EU) No 305/2014

(Text with EEA relevance)

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(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:

- Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in (1) animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) Propionic acid, sodium propionate and ammonium propionate were authorised for a period of 10 years as feed additives for ruminants, pigs and poultry by Commission Implementing Regulation (EU) No 1222/2013² and for all animal species other than ruminants, pigs and poultry by Commission Implementing Regulation (EU) No $305/2014^3$.
- In accordance with Article 14(1) of Regulation (EC) No 1831/2003, applications were (3) submitted for the renewal of the authorisation of propionic acid, sodium propionate and ammonium propionate for all animal species, requesting the additives to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. Those applications were accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 3 July 2024⁴ and 17 September 2024⁵ that propionic acid, sodium propionate and ammonium propionate remain safe for all terrestrial animal species, the consumer and

Feltkode ændret

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

Commission Implementing Regulation (EU) No 1222/2013 of 29 November 2013 concerning the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives for ruminants, pigs and poultry http://data.europa.eu/eli/reg_impl/2013/1222/oj). (OJ L 320, 30.11.2013.

Commission Implementing Regulation (EU) No 305/2014 of 25 March 2014 concerning the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives for all animal species other than ruminants, pigs and poultry (OJ L 90, 26.3.2014, p. 12, http://data.europa.eu/eli/reg_impl/2014/305/oj).

EFSA Journal, 22(8), e8938. https://doi.org/10.2903/j.efsa.2024.8938. EFSA Journal, 22(10), e9068. https://doi. org/10.2903/j.efsa.2024.9068.

EFSA Journal,22(10), e9020. https://doi.org/10.2903/j.efsa.2024.9020.

the environment under the authorised conditions. Regarding user safety, it concluded that propionic acid is corrosive to the skin while sodium and ammonium propionate are also corrosive to the eyes and respiratory tract. Sodium propionate is not a skin sensitiser. Any exposure of these additives to users is considered a risk. The Authority considered that there is no need for assessing the efficacy of propionic acid, sodium propionate and ammonium propionate in the context of the renewal of the authorisation, as the applications for renewal of the authorisations do not include proposals for amending or supplementing the conditions of the original authorisations that would have an impact on the efficacy of the additives.

- (5) By letter of 11 September 2024, the applicant withdrew the application for the renewal of the authorisation as regards the use of propionic acid, sodium propionate and ammonium propionate for aquatic animals.
- (6) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessments carried out regarding the methods of analysis of propionic acid, sodium propionate and ammonium propionate as feed additives are valid and applicable for the current applications. Those previous assessments 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 3 July 2024 and 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.
- (7) In view of the above, the Commission considers that propionic acid, sodium propionate and ammonium propionate satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of these additives 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 additives.
- (8) As a consequence of the renewal of the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives, Implementing Regulations (EU) No 1222/2013 and (EU) No 305/2014 should be repealed accordingly.
- (9) 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 substances specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives, is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulations (EU) No 1222/2013 and No 305/2014

Implementing Regulations (EU) No 1222/2013 and No 305/2014 are repealed.

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Article 3 Transitional measures

The feed additives propionic acid, sodium propionate and ammonium propionate, as authorised by Commission Implementing Regulations (EU) No 1222/2013 and No 305/2014 and feed containing them, which are produced and labelled before [12 months after 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.

Article 4 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

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