

Assessment of the feed additive consisting of propionic acid for all terrestrial animal species for the renewal of its authorisation (Eastman Chemical B.V., Perstorp AB, Dow Europe GmbH, BASF SE)

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Abstract

Propionic acid is currently authorised as a technological additive (functional group: silage additives) for all animal species. The applicants requested for the renewal of the authorisation of propionic acid when used as a feed additive for all terrestrial animal species. The applicants have provided evidence that the additive in the market complies with the conditions of the authorisation. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) confirms that the use of propionic acid under the current authorised conditions of use is safe for the target species, the consumers and the environment. Regarding user safety, the additive is corrosive to the skin and any exposure to users is considered a risk. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

KEYWORDS

efficacy, propionic acid, renewal, safety, silage additive, technological additive

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest 1 year before the expiry date of the authorisation.

The European Commission received a request from Eastman Chemical B.V.,² Perstorp AB,³ Dow Europe GmbH⁴ and BASF SE⁵ for the renewal of the authorisation of the additive consisting of propionic acid, when used as a feed additive for all terrestrial animal species (category: technological additive; functional group: silage additives). During the assessment, the applicants requested a change in the target species excluding from the application for authorisation all the aquatic animals; therefore, the current assessment covers only all terrestrial animals.⁶

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 14(1) (renewal of the authorisation). The dossier was received on 21 December 2022 and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00881>. The particulars and documents in support of the application were considered valid by EFSA as of 17 July 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicants, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of propionic acid, when used under the proposed conditions of use (see Section 3.1.2).

1.2 | Additional information

The additive is currently authorised as a silage additive, preservative and flavouring compound for use in all animal species (1k280).⁷

EFSA FEEDAP Panel issued several opinions on the safety and efficacy of propionic acid when used in feed for all animal species (EFSA FEEDAP Panel, 2011a, 2011b, 2012).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicants in the form of a technical dossier⁸ in support of the authorisation request for the use of propionic acid as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 17 July 2023 to 17 October 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002⁹ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's

¹Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

²Eastman Chemical B.V., Watermanweg 70 Rotterdam, Netherlands.

³Perstorp Specialty Chemicals AB. Industriparken, 284 80 Perstorp, Sweden.

⁴Dow AgroSciences Switzerland S.A., Bachtobelstrasse 4 Horgen, Switzerland.

⁵BASF SE, Carl-Bosch-Str. 38 Ludwigshafen, Germany.

⁶Technical dossier/2024-07-01 Letter EC Partial withdrawal Propionic acid_conf.pdf.

⁷Commission 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. OJ L 320, 30.11.2013, p. 16. To add the regulation from 2014 to add additional species. 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. Commission implementing regulation (EU) 2017/53 of 14 December 2016 concerning the authorisation of butan-1-ol, hexan-1-ol, octan-1-ol, nonan-1-ol, dodecan-1-ol, heptan-1-ol, decan-1-ol, pentan-1-ol, ethanol, acetaldehyde, propanal, butanal, pentanal, hexanal, octanal, decanal, dodecanal, nonanal, heptanal, undecanal, 1,1-diethoxyethane, formic acid, acetic acid, propionic acid, valeric acid, hexanoic acid, octanoic acid, decanoic acid, dodecanoic acid, oleic acid, hexadecanoic acid, tetradecanoic acid, heptanoic acid, nonanoic acid, ethyl acetate, propyl acetate, butyl acetate, hexyl acetate, octyl acetate, nonyl acetate, decyl acetate, dodecyl acetate, heptyl acetate, methyl acetate, methyl butyrate, butyl butyrate, pentyl butyrate, hexyl butyrate, octyl butyrate, ethyl decanoate, ethyl hexanoate, propyl hexanoate, pentyl hexanoate, hexyl hexanoate, methyl hexanoate, ethyl formate, ethyl dodecanoate, ethyl tetradecanoate, ethyl nonanoate, ethyl octanoate, ethyl propionate, methyl propionate, ethyl valerate, butyl valerate, ethyl hex-3-enoate, ethyl hexadecanoate, ethyl trans-2-butenate, ethyl undecanoate, butyl isovalerate, hexyl isobutyrate, methyl 2-methylbutyrate, hexyl 2-methylbutyrate, triethyl citrate, hexyl isovalerate and methyl 2-methylvalerate as feed additives for all animal species. OJ L 13, 17.1.2017, p. 1.

⁸Dossier reference: FEED-2022-11871.

⁹Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

Executive Director laying down practical arrangements concerning transparency and confidentiality,¹⁰ a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 20 September to 11 October 2023 for which no comments were received.

The FEEDAP Panel used the data provided by the applicants together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' (elicitation) knowledge, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the propionic acid in animal feed are valid and applicable for the current application.¹¹

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety, and the efficacy of propionic acid is in line with the principles laid down in Regulation (EC) No 429/2008¹² and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

Propionic acid is currently authorised as a technological additive (functional group: silage additives) for all animal species. This assessment regards the renewal of the authorisation of propionic acid as a silage additive for all terrestrial animal species.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

The additive is currently authorised with a purity of at least 99.5%, $\leq 0.01\%$ non-volatile residue when dried at 140°C to constant weight and $\leq 0.1\%$ aldehydes expressed as formaldehyde. The applicants requested to modify the specification of $\leq 0.1\%$ aldehydes expressed as formaldehyde, to $\leq 0.1\%$ aldehydes expressed as propionaldehyde, to align this specification to the current authorisation of propionic acid as preservative in feed. The FEEDAP Panel consider this change acceptable since no impact on the safety of the additive is expected.

The additive is produced by chemical synthesis. The applicants state that the manufacturing process has not been modified since the original authorisation.

Four manufacturers submitted data to characterise the additive. Analytical data to confirm the specification was provided from at least five batches per company¹³ and at least three batches for each company of the additive were analysed for aldehydes¹⁴ and non-volatile residues.¹⁵ The results showed an average of 99.8% propionic acid (99.7%–99.9%). Aldehydes (expressed as propionaldehyde) were found to be $< 0.01\%$ – 0.05% and non-volatile residues 0.0005%– $< 0.05\%$. Water content was analysed in the same batches showing an average content of 0.03% (0.01%–0.05%).

Three batches from each manufacturer were analysed for lead, mercury, cadmium (except for company C) and arsenic.¹⁶ All values were below the respective LOD¹⁷ and LOQs,^{18,19} except for those from company A for which the following values were found: 0.04 µg/L cadmium (0.027–0.053), 0.04 µg/L lead (0.025–0.046), 0.11 µg/L mercury (0.027–0.274).

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns.

¹⁰Decision <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>.

¹¹Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

¹²Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

¹³Six batches for company A, five batches for company B, five batches for company C and five batches for company D.

¹⁴Six batches for company A, three batches for company B, five batches for company C and three batches for company D.

¹⁵Five batches for company A, three batches for company B, five batches for company C and three batches for company D.

¹⁶Annex_II_08_Impurities_a_conf.pdf; Annex_II_02_Impurities-HM_b_confidential.pdf; Annex_II_01_CoA_c_confidential.pdf; Annex_II_04b_Impurities-HM-EN_d_conf.pdf.

¹⁷LOD for arsenic in each batch: 0.0161 µg/L, 0.163 µg/L and 0.0169 µg/L, originally expressed as ppb.

¹⁸LOQ: 0.5 mg/kg arsenic, 0.5 mg/kg lead, 0.2 mg/kg mercury and 0.2 mg/kg cadmium.

¹⁹LOQ: 0.1 µg/L arsenic, 0.02 µg/L cadmium, 0.05 µg/L lead and 0.03 µg/L mercury.

No new data were provided regarding the physico-chemical properties or stability of the additive. Since no changes were introduced in the manufacturing process, the data described in the previous opinion (EFSA FEEDAP Panel, 2011b) still apply.

3.1.2 | Conditions of use

The additive is currently authorised as a silage additive for use in feed at a maximum content in complete feed of 30,000 mg/kg for pigs and 10,000 mg/kg for poultry. It is also authorised in ruminants and all animal species other than pigs and poultry with no minimum and maximum content in feed.

Under 'other provisions' it is stated:

1. The simultaneous use of other organic acids at the maximum permitted doses is contraindicated.
2. The additive shall be used in easy to ensile material.
3. Simultaneous use with other sources of the active substance shall not exceed the authorised maximum content.
4. For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling.

The applicants did not request to change the current conditions of the authorisation except for the request to exclude aquatic species from the authorisation.²⁰

3.2 | Safety

In the scientific opinion adopted in 2011b, regarding the safety for the target species, the FEEDAP Panel concluded that 'large differences exist in the tolerance to propionic acid between different animal species. Poultry appears to be the most sensitive, followed by pigs; ruminants are rather insensitive. The maximum safe level of propionic acid for poultry is 10,000 mg/kg complete feed and for pigs 30,000 mg/kg complete feed. The corresponding maximum concentrations in water for drinking would be 4000 mg/L for poultry and 10,000 mg/L for pigs. Ruminants show a high tolerance to propionic acid, the ruminal production being considerably higher than a reasonable feed supplementation. This conclusion is extended to horses and rabbits. The use of propionic acid as a silage additive without a quantitative restriction of propionic acid supplementation would not affect the safety of target animals'.

No concern for the consumers and environment was expected from the use of propionic acid in animal nutrition at the recommended above-mentioned levels.

Regarding the safety for the users, the FEEDAP Panel concluded that propionic acid is corrosive to skin and mucous membranes, and strongly corrosive to the eyes. However, no data on sensitising effects were available (EFSA FEEDAP Panel, 2011b).

The applicants stated that no adverse effects or incidents/accidents have been reported from the use of the feed additive since the first authorisation of the product.²¹

In line with the requirements established in the EFSA Guidance on the renewal (EFSA FEEDAP Panel, 2021), the applicants performed an extensive literature search (ELS) to support that the additive remains safe for target species, consumers, users and the environment, under the approved conditions.²² The literature search focused on propionic acid and propionates. The timeframe considered was from 2012 to 2022 and the strategy followed was reported. The applicants searched in several relevant databases.²³ In addition to the automatic ELS, an independent manual search of relevant articles for the safety for the target species was conducted.

The ELS and the manual search identified a total of 62 publications potentially relevant for the safety for the target species (39 out of the 172 found in the ELS and 23 out of the 60 hits from the manual search). Four of the 62 relevant publications were EFSA opinions (EFSA ANS Panel, 2014, 2016; EFSA FEEDAP Panel, 2011a, 2011b, 2012).

Moreover, the literature search highlighted 11 potentially relevant publications for the safety for the consumer, two of which were EFSA opinions (EFSA ANS Panel, 2014, 2016) and four publications for the safety for the environment and four publications for the safety for the user, two of which were EFSA opinions (EFSA FEEDAP Panel, 2011a, 2011b).

None of the papers reviewed provided information relevant to the safety for the target species, consumers, user and the environment that would lead the Panel to modify its previous conclusions. Therefore, considering the above and the fact that the manufacturing of the additive, specifications and conditions of use have not been modified, the FEEDAP Panel concludes that propionic acid remains safe for the target species (all terrestrial animal species), consumers and the environment under the current conditions of authorisation.

²⁰Technical dossier/2024-07-01 Letter EC Partial withdrawal Propionic acid_conf.pdf.

²¹Annex_III_01_Monitoring_report_b_Conf.pdf; Annex_III_01_Monitoring_report_c_Conf.pdf.

²²Commission 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. OJ L 320, 30.11.2013, p. 16.

²³Annex_III_02_Literature_search_Conf.pdf; platforms consulted: Livivo, NCBI, Toxinfo.

The Panel notes that propionic acid is classified under Classification, labelling and packaging (CLP) Regulation EC No 1272/2008 as 'Skin corrosive 1B'.²⁴ Therefore, FEEDAP Panel concludes that propionic acid is corrosive and that any exposure by any route is considered a risk.

3.3 | Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

4 | CONCLUSIONS

The applicants provided evidence that the additive currently in the market complies with the existing conditions of the authorisation. The FEEDAP Panel concludes that the use of propionic acid under the current authorised conditions of use remains safe for the target species (all terrestrial animal species), the consumers and the environment.

Regarding user safety, the additive is corrosive to the skin and any exposure to users is considered a risk.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

ABBREVIATIONS

| | |
|--------|---|
| ANS | EFSA Scientific Panel on Additives and Nutrient Sources added to Food |
| CAS | Chemical Abstracts Service |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Chemical Substances |
| EURL | European Union Reference Laboratory |
| FAO | Food Agricultural Organization |
| FEEDAP | EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed |
| JECFA | The Joint FAO/WHO Expert Committee on Food Additives |
| LOD | limit of detection |
| LOQ | limit of quantification |
| WHO | World Health Organization |

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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²⁴Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) OJ L 353, 31.12.2008, p. 1–1355.

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