

# Safety and efficacy of a feed additive consisting of fumaric acid for all animal species for the renewal of its authorisation and extension of use (Life SUPPLIES NV)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | Roberto Edoardo Villa | Giovanna Azimonti | Eleftherios Bonos | Henrik Christensen | Mojca Durjava | Birgit Dusemund | Ronette Gehring | Boet Glandorf | Maryline Kouba | Marta López-Alonso | Francesca Marcon | Carlo Nebbia | Alena Pechová | Miguel Prieto-Maradona | Ilen Röhe | Katerina Theodoridou | Jaime Galobart | Paola Manini | Alberto Navarro-Villa | Fabiola Pizzo | Daniel Pagés Plaza | Anita Radovnikovic | Maria Vittoria Vettori | Angelica Amaduzzi

Correspondence: [feedap@efsa.europa.eu](mailto:feedap@efsa.europa.eu)

## Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the assessment of the application for the renewal of the authorisation of fumaric acid as a technological and sensory additive (functional groups: preservative and flavouring compounds, respectively) and for a new use of the additive as a technological additive (functional group: acidity regulator) for all animal species. The applicant provided evidence that the additive currently in the market complies with the existing conditions of authorisation. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that fumaric acid remains safe under the authorised conditions of use for the terrestrial animals, consumers and the environment. However, the Panel cannot conclude on the safety for the aquatic animals under all authorised condition of use. Fumaric acid is irritant to skin, eyes and respiratory tract, and should be considered a skin and respiratory sensitiser due to the presence of nickel. The Panel also considers that the new use of the additive as an acidity regulator under proposed conditions of use would not introduce risks not already considered. There is no need to assess the efficacy of the additive in the context of the renewal of the authorisation (for its use as preservative and flavouring compound). The Panel is not in the position to conclude on the efficacy of fumaric acid as an acidity regulator in feed.

## KEYWORDS

acidity regulator, extension of use, flavouring, fumaric acid, preservative, renewal, technological additive

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## 1 | INTRODUCTION

### 1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7. Also, 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 Life SUPPLIES NV<sup>2</sup> for the renewal of the authorisation of the additive consisting of fumaric acid, when used as a feed additive for all animal species (category: technological additive and sensory additives; functional group: preservative and flavouring compounds), and for a new use of the additive as an acidity regulator (category: technological additives, functional group: acidity regulator) for all animal species.

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 4(1) (authorisation of a feed additive or new use of a feed additive and under Article 14(1) (renewal of the authorisation). The dossier was received on 01 August 2023 and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00539>. The particulars and documents in support of the application were considered valid by EFSA as of 16 October 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, 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 fumaric acid, when used under the proposed conditions of use (see Section 3.1.2).

### 1.2 | Additional information

Fumaric acid is currently authorised as a preservative (1a297)<sup>3</sup> and as a flavouring compound in feed for all animal species (2b08025).<sup>4</sup> EFSA issued two opinions on the safety and efficacy of fumaric acid for all animal species, one as a flavouring (EFSA FEEDAP Panel, 2012) and another as a preservative (EFSA FEEDAP Panel, 2013). The applicant has requested the renewal of the authorisation and is also seeking the authorisation for a new use of fumaric acid as an acidity regulator.

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier<sup>5</sup> in support of the authorisation request for the use of fumaric acid as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 16 October 2023 to 16 January 2023; the comments received were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002<sup>6</sup> 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 Executive Director laying down practical arrangements concerning transparency and confidentiality,<sup>7</sup> 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 August to 10 September 2024 for which no comments were received.

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 fumaric acid in animal feed are valid and applicable for the current application.<sup>8</sup>

<sup>1</sup>Regulation (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.

<sup>2</sup>LIFE SUPPLIES PLC Industrielaan 25 Olen – Belgium.

<sup>3</sup>Commission Implementing Regulation (EU) No 1078/2013 of 31 October 2013. OJ L 292, 1.11.2013, p. 7.

<sup>4</sup>Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01). OJ C 50, 25.2.2004, p. 1.

<sup>5</sup>Dossier reference: FEED-2023-17122

<sup>6</sup>Regulation (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.

<sup>7</sup>Decision <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>.

<sup>8</sup>Evaluation 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

## 2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of fumaric acid is in line with the principles laid down in Regulation (EC) No 429/2008<sup>9</sup> and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

## 3 | ASSESSMENT

The additive fumaric acid is currently authorised for use as a technological additive (functional group: preservative) and as a sensory additive (functional group: flavouring compound) for all animal species. The applicant requests the renewal of the authorisation of fumaric acid as a preservative and flavouring compound for all animal species, and the new use as technological additive (functional group: acidity regulator) for all animal species.

### 3.1 | Characterisation

#### 3.1.1 | Characterisation of the additive

The additive is authorised with a purity of 99.5% of fumaric acid (Chemical Abstracts Service (CAS) number 110-17-8, chemical formula  $C_4H_4O_4$ , molecular weight 116.07 g/mol).

The additive is produced by chemical synthesis, by isomerisation of maleic acid; the applicant declared that no changes in the manufacturing process or the composition of the additive have been introduced since the last authorisation.

Data on the characterisation of the additive have been submitted by three manufacturers. Analytical data to confirm the specifications were provided for 15 batches<sup>10</sup> of the additive (five per company), showing an average of 99.7% (99.7%–99.9%) fumaric acid.

Three batches of each manufacturer were analysed for impurities.<sup>11</sup> Cadmium, lead, mercury, arsenic and nickel concentration were below the corresponding limit of quantification (LOQ) in all batches except one batch from one manufacturer, which showed a content of nickel of 0.3 mg/kg.<sup>12</sup>

Polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs were analysed in the nine batches.<sup>13</sup> The calculated upper bound concentrations were 0.0759 (0.0690–0.0790) ng WHO-PCCD/F TEQ/kg for the sum of dioxins and 0.116 (0.106–0.121) ng WHO-PCCD/F + PCB TEQ/kg for the sum of dioxins and dioxin-like PCBs. The upper bound sum of non-dioxin-like PCBs was 0.0720 (0.0654–0.0750) ng/kg (all expressed in 88% dry matter).

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, with the exception of nickel, which is addressed in the section on the safety for the user (see Section 3.2).

The feed additive fumaric acid is a white crystalline solid. Fumaric acid is slightly<sup>14</sup> soluble in water (7 g/L at 25°C).<sup>15</sup> Additional data<sup>16</sup> confirmed the shelf-life of fumaric acid of 2 years, when stored at temperature of 23–35°C and protected from direct sunlight, which confirmed the previous conclusions on shelf-life. No other new data were provided regarding the physico-chemical properties or stability of the additive. Since no changes were introduced in the manufacturing process, the conclusions reached in the previous opinion (EFSA FEEDAP Panel, 2013) still apply.

<sup>9</sup>Commission 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.

<sup>10</sup>Annex\_II\_1\_3\_Thirumalai\_CoAs, Annex\_II\_1\_3\_Vertellus\_CoAs, Annex\_II\_1\_3\_Yantai\_CoAs.pdf. Methods used: titration and acidimetry.

<sup>11</sup>Annex\_II\_1\_4\_Thirumalai\_Heavy\_Metals, Annex\_II\_1\_4\_Vertellus\_Heavy\_Metals, Annex\_II\_1\_4\_Yantai\_Heavy\_Metals.

<sup>12</sup>LOQ: Cadmium 0.01 mg/kg, lead 0.05 mg/kg, mercury 0.05 mg/kg, arsenic 0.1 mg/kg, nickel 0.1 mg/kg.

<sup>13</sup>Annex\_II\_1\_4\_Thirumalai\_Dioxins\_PCBs\_Redacted.pdf, Annex\_II\_1\_4\_Vertellus\_Dioxins\_PCBs.pdf, Annex\_II\_1\_4\_Yantai\_Dioxins\_PCBs.pdf.

<sup>14</sup>Solubility term follows Table 2 of the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021).

<sup>15</sup>Annex\_II\_5\_2\_SDS.pdf.

<sup>16</sup>Annex\_II\_4\_1\_Thirumalai\_Stability\_Earmarked.pdf and Annex\_II\_4\_1\_Yantai\_Stability\_Redacted.pdf.

### 3.1.2 | Conditions of use

The additive is currently authorised as:

- (i) Preservative (1a297) for use in feed for pigs and poultry at a maximum content of 20,000 mg/kg, young animals fed with milk replacers at a maximum content of 10,000 mg/kg.<sup>17</sup> It is also authorised in all animal species other than pigs, poultry and young animals fed with milk replacers with no minimum and maximum content in feed.

Under 'other provisions' it is stated:

1. For safety: breathing protection, glasses and gloves shall be used during handling

- (ii) Flavouring compound (2b08025) for all animal species with no minimum and maximum content in feed.

Under 'other provisions' it is stated:

1. The additive shall be incorporated into the feed in the form of a premixture.
2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.
3. The recommended maximum content of the active substance shall be: 5 mg/kg of complete feedingstuff with a moisture content of 12%.
4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuffs with a moisture content of 12%: 5 mg/kg'.
5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feeding stuffs, if the following content of the active substance in complete feedingstuffs with a moisture content of 12% is exceeded: 5 mg/kg.

The applicant has not requested any changes to the existing authorisation conditions for the use of fumaric acid as a preservative. However, the applicant proposed aligning the conditions for its use as a flavouring compound with those established for its use as a preservative.

In addition, the applicant is seeking authorisation for the use of fumaric acid as an acidity regulator at a maximum content of 20,000 mg/kg for pigs and poultry, 10,000 mg/kg for young animals fed with milk replacers and with no minimum and maximum content in feed for all animal species other than pigs, poultry and young animals fed with milk replacers.

## 3.2 | Safety

The applicant 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.<sup>18</sup>

In its previous assessment (EFSA FEEDAP Panel, 2012), the FEEDAP Panel concluded that fumaric acid, at the maximum recommended use level of 5000 mg/kg complete feed, is safe for all animal species, the consumer and the environment, but should be considered irritant to the respiratory tract, skin and eyes and should be considered a skin sensitiser. In its subsequent assessment (EFSA FEEDAP Panel, 2013), the FEEDAP Panel concluded that fumaric acid is safe for pigs and poultry up to 20,000 mg/kg in complete diets, with a sufficient margin of safety and does not require a maximum content for ruminants due to higher tolerance levels. For young mammals on milk replacers, a provisional safe limit of 10,000 mg/kg was identified without an additional safety margin. In line with the requirements established in the EFSA Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021), evidence should be provided that the additive remains safe for the target species and that the additive is safe for fish (salmonids). The applicant performed an extensive literature search (ELS). The timeframe considered was from 2013 to 2024 and the strategy followed was reported. The applicant searched in three databases (CAB Abstracts®, FSTA® and GRANT INDEX). The ELS identified a total of 27 publications potentially relevant, of which two were FEEDAP Panel opinions (EFSA FEEDAP Panel, 2013, 2015).

None of the papers reviewed provided information relevant to the safety for the terrestrial animals that would lead the Panel to modify its previous conclusions. Two studies were found which provided information on fish.

In the first one, Pandey and Satoh (2014)<sup>19</sup> investigated the effects of dietary supplementation with various organic acids on the growth performance, nutrient retention and phosphorus utilisation in rainbow trout (*Oncorhynchus mykiss*) over a 12-week period. The study followed a randomised design with duplicate groups of 25 fish each, fed with a basal diet or with the same diet supplemented with 10,000 mg/kg of fumaric acid, formic acid or acetic acid. In addition, a positive control diet containing 0.5% inorganic phosphorus was included. The fish were fed *ad libitum* twice daily and growth parameters

<sup>17</sup>Mg of fumaric acid per kg of milk replacer.

<sup>18</sup>Annex\_V.pdf and Annex\_V\_updated\_17JUN24\_Conf.pdf.

<sup>19</sup>Pandey\_et\_al\_2014.pdf.

such as specific growth rate (SGR) and feed conversion ratio (FCR) were recorded, along with mineral content in the whole body and bones, and nutrient retention and excretion. The supplementation with 1% fumaric acid did not cause any adverse effects on the performance parameters measured.

In the second study (Das Neves et al., 2022),<sup>20</sup> Nile tilapia juveniles (*Oreochromis niloticus*) were distributed into three groups and fed diets supplemented with varying levels of fumaric acid (0, 5000, 10,000, 15,000, 20,000 or 30,000 mg/kg) over a 35-day period, to evaluate its effects on growth performance (feed intake, weight gain, feed and protein efficiency) and intestinal villi morphology. No negative adverse effects were observed on the growth parameters measured. Villi height and width were not consistently influenced by fumaric acid concentration and by time. However, no pathological signs were detected in the villi.

The Panel notes that the data available on the safety of fumaric acid on aquatic animals is scarce. The two studies assessed share several limitations (e.g. lack of overdose in the first study, short duration in the second study, absence of blood parameters analysis, necropsy and histopathology). Although no adverse effects were observed, the Panel considers that none of them provides sufficient information to allow the Panel to conclude on the safety of fumaric acid for aquatic species under the current conditions of the authorisation.

The Panel notes that fumaric acid is classified under Classification, labelling and packaging (CLP) Regulation EC No 1272/2008 as 'Eye irritant 2'.<sup>21</sup> Due to the presence of nickel, the additive should be considered a skin and respiratory sensitiser. Furthermore, the FEEDAP Panel notes that the European Directive 2022/431<sup>22</sup> set an occupational exposure limit (OEL) of 0.01<sup>23</sup> and 0.1<sup>24</sup> mg/m<sup>3</sup> for both respirable and inhalable fraction, respectively as nickel meets the criteria for classification as carcinogenic (category 1A). Therefore, to reduce the risk, the FEEDAP Panel considers that the exposure of the users should be minimised. Thus, the FEEDAP Panel concludes that fumaric acid is an irritant to eyes and respiratory tract and should be considered a skin and respiratory sensitiser.

Based on the above and the fact that the manufacturing and composition of the additive have not been modified, the FEEDAP Panel concludes that fumaric acid remains safe for the terrestrial animals, consumers and the environment under the authorised conditions of use as preservative. However, the Panel cannot conclude on the safety for the aquatic animals under all authorised conditions of use. The additive should be considered a skin/eye irritant and a respiratory/dermal sensitiser.

The Panel also considers that the proposed alignment of the conditions of use for fumaric acid as a flavouring compound with those established for its use as a preservative and its new uses as an acidity regulator would not introduce risks not already considered, considering that the conditions of use and the maximum use levels proposed are the same for all uses.

### 3.3 | Efficacy

The present application for renewal of the authorisation of fumaric acid as a preservative and as a flavouring compound does not include a proposal for amending the conditions of the original authorisation that would have an impact on the efficacy of the additive.

The applicant requested the authorisation of fumaric acid as an acidity regulator. No evidence was provided by the applicant to support the efficacy of fumaric acid as an acidity regulator in feed. Therefore, in the absence of adequate data, the FEEDAP Panel cannot conclude on the efficacy of fumaric acid as an acidity regulator when used in feed for all animal species.

## 4 | CONCLUSIONS

The applicant provided evidence that the additive currently in the market complies with the existing conditions of authorisation.

The FEEDAP Panel concludes that fumaric acid remains safe under the authorised conditions of use for the terrestrial animals, consumers and the environment. However, the Panel cannot conclude on the safety for the aquatic animals under all authorised conditions of use.

Fumaric acid is irritant to skin, eyes and respiratory tract, and should be considered a skin and respiratory sensitiser.

The Panel also considers that the new use of the additive as an acidity regulator under proposed conditions of use would not introduce risks not already considered.

<sup>20</sup>Das\_Neves\_et\_al\_2022.pdf.

<sup>21</sup>Regulation (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. OJ L 353, 31.12.2008, p. 1–1355.

<sup>22</sup>Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 88/2, 16.3.2022, p. 14.

<sup>23</sup>The limit value (10) shall apply from 18 January 2025.

<sup>24</sup>From 18 January 2025. A limit value of 0.05 mg/m<sup>3</sup> shall apply.

There is no need to assess the efficacy of the additive in the context of the renewal of the authorisation (for its use as preservative and flavouring compound). The Panel is not in the position to conclude on the efficacy of fumaric acid as an acidity regulator in feed.

## ABBREVIATIONS

ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
DM	dry matter
ELS	extensive literature search
FCR	feed conversion ratio
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
PCDDs	Polychlorinated dibenzo- <i>p</i> -dioxins
PCDFs	polychlorinated dibenzofurans
PCBs	dioxin-like polychlorinated biphenyls
SGR	specific growth rate
WHO	World Health Organization

## ACKNOWLEDGEMENTS

The Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Montserrat Anguita and Matteo Lorenzo Innocenti.

## 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](mailto:interestmanagement@efsa.europa.eu).

## REQUESTOR

European Commission

## QUESTION NUMBER

EFSA-Q-2023-00539

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## PANEL MEMBERS

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Anna Dioni, Maria Dulak-Lis, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Orsolya Holczknecht, Laura Iancu, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Ilen Röhe, and Katerina Theodoridou.

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**How to cite this article:** EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Villa, R. E., Azimonti, G., Bonos, E., Christensen, H., Durjava, M., Dusemund, B., Gehring, R., Glandorf, B., Kouba, M., López-Alonso, M., Marcon, F., Nebbia, C., Pechová, A., Prieto-Maradona, M., Röhe, I., Theodoridou, K., Galobart, J., Manini, P., ... Amaduzzi, A. (2024). Safety and efficacy of a feed additive consisting of fumaric acid for all animal species for the renewal of its authorisation and extension of use (Life SUPPLIES NV). *EFSA Journal*, 22(10), e9019. <https://doi.org/10.2903/j.efsa.2024.9019>