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Assessment of the feed additive consisting of orthophosphoric acid for all animal species for the renewal of its authorisation (Prayon S.A.; Chemische Fabrik Budenheim KG; BK Giulini GmbH)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the application for renewal of orthophosphoric acid as a technological additive (functional group: preservatives) for all animal species. The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation. There is no evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concluded that the additive remains safe for all animal species provided that the optimal Ca:P ratio is maintained. Additionally, the FEEDAP Panel concluded that orthophosphoric acid remains safe for the consumer and the environment under the authorised conditions of use. Regarding the user safety, orthophosphoric acid is corrosive to the skin and eyes and should be considered as hazardous to the respiratory tract. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

Keywords: technological additives, preservatives, orthophosphoric acid, safety, efficacy, renewal

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Table of contents

1. Introduction

1.1. Background and terms of reference

Regulation (EC) No 1831/2003[1] 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 one year before the expiry date of the authorisation.

The European Commission received a request from Prayon S.A., Chemische Fabrik Budenheim KG and BK Giulini GmbH[2,3] for the renewal of the authorisation of the additive consisting of orthophosphoric acid, when used as a feed additive for all animal species (category: technological; functional group: preservatives).

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). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 13 February 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 orthophosphoric acid, when used under the proposed conditions of use (see **Section 3.1.2**).

1.2. Additional information

The additive consists of orthophosphoric acid. EFSA issued one opinion on the safety and efficacy of this product when used in feed for animal species (EFSA FEEDAP Panel, 2013).[4] Additionally, the EFSA Food Additives and Flavourings (FAF) Panel issued an opinion on phosphoric acid, phosphates and polyphosphates when used as food additives (EFSA FAF Panel, 2019).

Orthophosphoric acid is currently authorised for use in feed for all animal species in the European Union (1a338).[5] The additive is also authorised as a food additive (E 338).[6]

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[7] in support of the authorisation request for the use of orthophosphoric acid as a feed additive. The dossier was received on 21 November 2022 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00812.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 13 February to 13 May 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[8] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the

[1] 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.
[2] Prayon S.A., Rue J. Wauters, 144 Engis – Belgium; Chemische Fabrik Budenheim KG, Rheinstraße 27 Budenheim - Germany; BK Giulini GmbH, Am Hafen 2 Ladenburg – Germany.
[3] Out of the three companies involved in the current application only Prayon S.A. and BK Giulini GmbH declare to manufacture the feed additive under assessment.
[4] EFSA Dossier reference: FAD-2010-0268.
[5] Commission Implementing Regulation (EU) No 1055/2013 of 25 October 2013 concerning the authorisation of Orthophosphoric acid as a feed additive for all animal species. OJ L 288, 30.10.2013, p. 57.
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20220720&qid=1675353765734&from=en
[7] Dossier reference: FEED-2022-10412.
[8] 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.

same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[9] a non-confidential version of the dossier has been published on Open.EFSA at https://open.efsa.europa.eu/questions/FEED-Q-2022-00812.

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,[9] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 15 May to 05 June 2023 for which no comments were received.

The FEEDAP Panel used the data provided by the applicant 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 active substance/agent in animal feed/marker residue in tissues are valid and applicable for the current application.[10]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of orthophosphoric acid is in line with the principles laid down in Regulation (EC) No 429/2008[11] and the relevant guidance document: the Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3. Assessment

The additive orthophosphoric acid is authorised as a technological additive (functional group: preservatives) in feed for all animal species and this is the assessment of the application for the renewal of its authorisation.

3.1. Characterisation

3.1.1. Characterisation of the additive

Orthophosphoric acid, also known as phosphoric acid or monophosphoric acid (CAS No 7664-38-2; EINECS number 231-633-2; molecular formula H_3PO_4; molecular weight 98.00 g/mol), has a specific weight (for 75% orthophosphoric acid at 30 °C) of 1,570 kg/m^3.[12]

The additive under assessment is currently authorised as a feed additive with the following specifications: preparation of orthophosphoric acid (67–85.7% H_3PO_4) w/w (aqueous solution), ≤ 10 mg volatile acid (as acetic acid)/kg, ≤ 200 mg chlorides (as chlorine)/kg and ≤ 1,500 mg sulfates (as $CaSO_4$)/kg. These specifications are identical to those of the food additive.

In the current application, additional specifications are set for impurities and contaminants as follows: ≤ 5 mg of nitrates/kg (as $NaNO_3$), ≤ 10 mg fluoride/kg, ≤ 1 mg arsenic/kg, ≤ 1 mg cadmium/kg, ≤ 1 mg of lead/kg and ≤ 1 mg mercury/kg.

Data on the characterisation of the additive were provided by two manufacturers. Orthophosphoric acid is produced from phosphate ore that can come from igneous phosphate ore or from sedimentary ore. In the original application, two manufacturing processes (the wet process and the electro-thermal process[13]) were described. In the current application, the applicants stated that only the wet manufacturing process is followed and that no changes in the manufacturing process have been applied since the authorisation of the additive.[14]

[9] Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[10] Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-OrthophosphoricGroup.pdf

[11] 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.

[12] 2.1 and 2.2 Identity and characterisation Revised 20230123.

[13] https://eippcb.jrc.ec.europa.eu/sites/default/files/2022-03/LVIC-AAF.pdf

[14] Manufacturing process.

Data on the batch-to-batch variation of four[15] and five[16] recent batches were provided by the two manufacturers. Analytical data confirmed the specifications of the additive showing the following average values: 85.0 (84.9–85.1)% and 75.1 (74.9–75.2)% (w/w) orthophosphoric acid (for each producer, respectively). In the batches from one producer, chloride values were below the limit of quantification (LOQ), the sulfates averaged 176 (140–232) mg/kg and volatile acids below the LOQ.[17] In the batches from the other producer, assessed in a concentrated form of the additive (93% orthophosphoric), chloride values were 1.8 (1.79–1.8) mg/kg, the sulfates 105 (74–135) mg/kg and volatile acids 0.56 (0.2–0.9) mg/kg.

The same batches[16,18] were analysed for other chemical impurities. The impurity analyses in batch samples from one producer were below the LOQ[19] except for fluorine and arsenic that averaged 5.25 mg/kg and 0.04 mg/kg, respectively. The analyses provided by the other producer were performed in a concentrated form of orthophosphoric acid (93%) and in the purified water used for the dilution.[20] Impurity results in the concentrated additive were below the LOQ[21] for cadmium, lead and mercury. Arsenic averaged 0.3 mg/kg, heavy metals 0.62 mg/kg and fluorine 0.3 mg/kg. The analytical values of water samples showed negligible levels of impurities.

Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and coplanar dioxin-like polychlorinated biphenyls (co-planar PCBs) in three batches from each producer were below the corresponding LOQ. For one producer, the calculated (upper bound) levels of dioxins and the sum of dioxins and dioxin-like-PCBs were 0.11 ng WHO-PCDD/F-TEQ/kg and 0.22-0.23-0.22 ng WHO-PCDD/F-PCB-TEQ/kg, respectively.[22] For the other producer, the calculated (upper bound) levels of dioxins and the sum of dioxins and dioxin-like-PCBs were 0.11 ng WHO-PCDD/F-TEQ/kg and 0.21-0.24-0.29 ng WHO-PCDD/F-PCB-TEQ/kg, respectively.[23]

The detected amounts of the above-described impurities do not raise safety concerns.

The additive is a liquid highly soluble in water (750–850 g/L).

No new data were provided regarding the physico-chemical properties of the additive. Since no changes were introduced in the additive's manufacturing process, the data described in the previous opinion (EFSA FEEDAP Panel, 2013) are considered relevant for the present assessment.

3.1.2. Conditions of use

Orthophosphoric acid is authorised as a technological (functional group: preservatives) feed additive in all animal species without a maximum recommended dose nor a withdrawal period.

The authorising regulation under other provisions states that:

- For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling.
- The content of phosphorus shall be indicated in the label of premixture.

The applicants have not requested to modify the current conditions of use.

3.2. Safety

The safety of the additive for the target species, the consumers, the users and the environment was assessed by the FEEDAP Panel in the previous opinion on orthophosphoric acid (EFSA FEEDAP Panel, 2013). The FEEDAP Panel concluded that the feed additive is safe for the target species, when used as a preservative provided that the optimal Ca:P ratio in the diets is maintained and thus, setting a maximum content for the additive was not considered necessary. The Panel also concluded that the use of orthophosphoric acid in animal nutrition under the proposed conditions would not give rise to concern for the consumers of animal products and the environment. Orthophosphoric acid was considered corrosive to skin and eyes and hazardous to the respiratory tract.

[15] Annex II.1.2_CoA_1.
[16] Annex II.1.3_CoA_2.
[17] Limit of quantification (LOQ): chlorides = 5 mg/kg; volatiles = 10 mg/kg.
[18] Annex II.1.2_CoA_1 and Annex II.1.6_CoA_1_LOQs Confidential.
[19] LOQ (mg/kg) from Prayon S.A. analysis: As = 0.01; Cd = 0.04; Cl = 5; F = 1; Fe = 0.2; heavy metals (Pb) = 5; Hg = 0.025; $NaNO_3$ = 1; Ni = 0.08; Pb = 0.2; SO_4 = 3; volatile acids = 10.
[20] Annex II.1.4_CoA_Concentrate and Annex II.1.5_CoA_Water.
[21] LOQ (mg/kg) from BK Giulini GmbH analysis: Cd = 0.1; Hg = 0.005; Pb = 0.1.
[22] Annex II.1.7_Dioxins_1 Confidential.pdf.
[23] Annex II.1.8_Dioxins_2 Confidential.pdf.

The applicants stated that since the previous authorisation in 2013, no reports of adverse effects, incidents or accidents for target species, consumers, users and the environment were received.

The applicants submitted a literature search to support the renewal of the authorisation of the feed additive for all species.

3.2.1. Extensive literature search

The applicant conducted a literature search on the safety of orthophosphoric acid covering the period 2013–2022 (23 November 2022 date of the literature search) across four cumulative databases (LIVIVO, NCBI, OVID, Toxinfo), 13 single databases (BGIA/Gestis, CAMEO, CDC/NIOSH, ChemSpider, CSIR-NISCAIR, ECHA, EPA ECOTOX, EPA HSN/CCID, ICH ICSH, NHSEED, NITE, NPIC) and 12 publisher databases (ACS pub, Bentham, Elsevier, Ingenta, Kluwer/LWW, Liebert, Oxford, RSC Pub, Sage, Springer, Taylor & Francis, Wiley Library). The inclusion and exclusion criteria applied in the search was fully described. A total of 34 results were retrieved from the bibliographic databases and, after the screen of two expert reviewers, 20 articles were identified to provide relevant information for the assessment of the safety of orthophosphoric acid for target animals, consumers, users and the environment. Only two of these papers contained information relevant for the safety of orthophosphoric acid for the consumers and the user, which are described below.

A publication on the genotoxic potential of orthophosphoric acid was identified (Yilmaz et al., 2014) reporting increased the mean tail length and mean tail intensity in *in vitro* comet assay in human lymphocytes. EFSA evaluated this report in the context of the assessment of orthophosphoric acid as a food additive and found the relevance of the findings reported in that study for risk assessment questionable (EFSA FAF Panel, 2019). The FEEDAP Panel, having reviewed the publication, confirmed the conclusions of the EFSA FAF Panel, and does not consider the results of this study as relevant of the genotoxic potential of the additive.

In the context of the safety for the users, the literature search identified one relevant publication (Johnson Jr et al., 2021), in which phosphoric acid and its salts were evaluated as cosmetic ingredients, confirming the corrosive properties of orthophosphoric acid.

3.2.2. Conclusions on safety

Based on the above and considering that manufacturing and composition of the feed additive have not been modified, the FEEDAP Panel considers that there is no evidence to reconsider the conclusions reached in the previous opinion regarding the safety of orthophosphoric acid. Thus, the FEEDAP Panel concludes that the additive remains safe under the approved conditions of use for the target species, the consumers and the environment. The FEEDAP Panel reiterates its previous conclusion that orthophosphoric acid is corrosive to the skin and eyes and hazardous for the respiratory tract.

3.3. Efficacy

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

4. Conclusions

The additive currently on the market complies with the conditions of authorisation. The FEEDAP Panel concludes that the use of orthophosphoric acid under the current authorised conditions of use remains safe for target species, consumers and the environment. Orthophosphoric acid is corrosive to skin and eye and hazardous to the respiratory tract.

The present application for renewal of the authorisation does not include a proposal for amending the conditions of the original authorisation that would have an impact on the efficacy of the additive.

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Abbreviations

AFC	EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
CAS	Chemical Abstracts Service
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOQ	limit of quantification
SCAN	Scientific Committee on Animal Nutrition
SCF	Scientific Committee on Food