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Statement on the safety and efficacy of phosphoric acid 60% on silica carrier (UD60) for all animal species

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Abstract

The additive UD60 (phosphoric acid 60% on silica carrier) is intended to be used as a technological additive (functional group: preservative) for all animal species. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) assessed the data provided by the applicant in the technical dossier. During the course of the assessment, the need for additional information in order to be able to deliver an opinion on the safety and efficacy of this additive was identified and notified to the applicant. The information requested covered the characterisation, the safety for the target species and the efficacy of the additive. The applicant has failed to provide the additional information. Therefore, considering the data provided in the original dossier and the absence of response from the applicant to the requests from EFSA, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive UD60 (phosphoric acid 60% on silica carrier) as a technological additive for all animal species.

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1. Introduction

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company PROCAAF S.A.S.² for authorisation of the product UD60 (phosphoric acid 60% on silica carrier) to be used as a feed additive (category: technological additives; functional group: preservatives) 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 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application.³ The particulars and documents in support of the application were considered valid by EFSA as of 17 June 2011.

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 product UD60 (phosphoric acid 60% on silica carrier), for all animal species and categories.

2. The application dossier

The present application concerns the product UD60 (phosphoric acid 60% on silica carrier) to be used as a technological additive (functional group: preservative) in feed for all animal species.

The European Commission received an application for the use of this product in feed for all animal species on 30 November 2010. This application was received by EFSA on 4 May 2011. EFSA immediately started the verification of the dossier to check whether all the documents and particulars requested in Article 7(3) of Regulation (EC) No 1831/2003 were provided. The dossier was considered valid for the start of the assessment on 17 June 2011. The scientific evaluation of the technical dossier started immediately. During the course of the assessment, the working group on Organic acids of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) identified the need for additional information in order to be able to deliver an opinion on the safety and efficacy of this additive. The information request was sent to the applicant on 22 July 2011 and covered the characterisation, the safety for the target species and the efficacy of the additive. In several occasions, the applicant requested extensions of the deadline to provide the information, which was eventually set to 14 December 2012. Since then, the applicant had been asked several times to answer EFSA's request but the data were never provided. Therefore, on 3 March 2020, EFSA notified the applicant its intention to finalise the assessment regarding the dossier of reference. In the absence of adequate information, the FEEDAP Panel is not in a position to characterise the additive and to assess its safety and efficacy.

The European Union Reference Laboratory (EURL) delivered its report on the methods of analysis for this dossier.⁴

3. Conclusions

Considering the limited data provided in the original dossier and the absence of response from the applicant to the requests from EFSA for additional information, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive UD60 (phosphoric acid 60% on silica carrier) as a technological additive for all animal species.

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

² PROCAAF S.A.S., via C. Menotti 3, 20030 Bovisio Masciago MB, Italy.

³ EFSA Dossier reference: FAD-2011-0011.

⁴ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-OrthophosphoricGroup.pdf>

4. Documentation as provided to EFSA/Chronology

Date	Event
23/02/2011	Dossier received by EFSA. Phosphoric acid 60% on silica carrier (UD60) for all animal species. Submitted by PROCAAF S.A.S.
04/05/2011	Reception mandate from the European Commission
17/06/2011	Application validated by EFSA – Start of the scientific assessment
17/09/2011	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
17/09/2011	Comments received from Member States
22/07/2011	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: structure of the dossier, safety for the target species and efficacy</i>
03/03/2020	Scientific assessment re-started
17/03/2020	Statement adopted by the FEEDAP Panel. End of the Scientific assessment

Abbreviations

EURL European Union Reference Laboratory
FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed