

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/505

of 23 March 2021

concerning the denial of authorisation of phosphoric acid 60 % on silica carrier as a feed additive belonging to the functional group of preservatives

(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 nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Orthophosphoric acid was authorised without a time limit by Directive 70/524/EEC as a feed additive for all animal species. The additive was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, two applications for re-evaluation of orthophosphoric acid were submitted to the Commission.
- (4) The first of those applications concerned a preparation of orthophosphoric acid (67 %-85,7 %) w/w (aqueous solution). That preparation was authorised by Commission Implementing Regulation (EU) No 1055/2013 ⁽³⁾ for 10 years as a feed additive for all animal species.
- (5) The second application was submitted for the re-evaluation of phosphoric acid 60 % on silica carrier as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'technological additives' and in the functional group 'preservatives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) No 1055/2013 of 25 October 2013 concerning the authorisation of a preparation of orthophosphoric acid as a feed additive for all animal species (OJ L 288, 30.10.2013, p. 57).

- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2020 ⁽⁴⁾ that considering the limited data provided in the original dossier and the absence of response from the applicant to the several requests from the Authority for additional information, initially on 22 July 2011 and finally on 3 March 2020, the Authority was not in a position to deliver an opinion on the safety and efficacy of phosphoric acid 60 % on silica carrier as a feed additive for all animal species.
- (7) In addition, on 8 May 2020 the Commission requested the applicant to communicate information on the follow-up of the application concerned, but no response was provided.
- (8) According to Article 5(1) of Regulation (EC) No 1831/2003, the applicant must adequately and sufficiently demonstrate, in accordance with the implementing measures ⁽⁵⁾ to Regulation (EC) No 1831/2003, that the additive satisfies the conditions for authorisation laid down in that Regulation.
- (9) As the applicant did not provide the requested information and data allowing the Authority to assess the safety and efficacy of phosphoric acid 60 % on silica carrier, it has not been established that, under the proposed conditions of use, the additive does not have an adverse effect on animal health, human health or the environment, and that it has at least one of the characteristics set out in Article 5(3) of Regulation (EC) No 1831/2003.
- (10) The assessment of phosphoric acid 60 % on silica carrier shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied. Accordingly, the authorisation of the additive should be denied.
- (11) Therefore, phosphoric acid 60 % on silica carrier, as an existing product within the meaning of Article 10 of Regulation (EC) No 1831/2003, as well as feed containing it, should be withdrawn from the market. However, a limited period should be allowed for the withdrawal from the market of the existing stocks of the additive and its premixtures, and feed containing them, in order to enable operators to comply properly with the withdrawal obligation.
- (12) 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

Denial of authorisation

The authorisation of phosphoric acid 60 % on silica carrier as a feed additive, belonging to the additive category 'technological additives' and to the functional group 'preservatives', is denied.

Article 2

Withdrawal from the market

1. Existing stocks of the additive referred to in Article 1, and of premixtures containing it, shall be withdrawn from the market by 13 October 2021.
2. Feed materials and compound feed intended for food-producing animals, which have been produced with the additive or the premixtures referred to in paragraph 1 before 13 October 2021, shall be withdrawn from the market by 13 April 2022.

⁽⁴⁾ *EFSA Journal* 2020;18(4):6064.

⁽⁵⁾ 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).

3. Feed materials and compound feed intended for non-food-producing animals, which have been produced with the additive or the premixtures referred to in paragraph 1 before 13 October 2021, shall be withdrawn from the market by 13 April 2023.

Article 3

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, 23 March 2021.

For the Commission
The President
Ursula VON DER LEYEN
