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EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 as a feed additive for poultry (holder of authorisation: Proteon Pharmaceuticals S.A.)

(Text with EEA relevance)

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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 such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 as a feed additive for use in complementary feed and in water for drinking. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation a preparation of the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 as a feed additive for all avian species, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘other zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 17 March 2021[2], 31 January 2023[3] and 26 November 2024[4] that, under the proposed conditions of use, the preparation of the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 (‘the preparation’) is safe for all avian species, consumers and the environment. It also concluded that the preparation is not a skin or eye irritant but should be considered a potential skin and respiratory sensitiser, while inhalation and dermal exposure is considered a risk. The Authority further concluded that the preparation has the potential to reduce the environmental contamination with *Salmonella* Enteritidis when used in water for drinking or liquid complementary feed for all poultry species. It considered that there is a need for specific requirements of post-market monitoring to address the potential selection and spread of resistant

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal 2021;19(5):6534. https://doi.org/10.2903/j.efsa.2021.6534.
[3] EFSA Journal 2023;21(3):7861. https://doi.org/10.2903/j.efsa.2023.7861.
[4] EFSA Journal. 2024;22:e9132. https://doi.org/10.2903/j.efsa.2024.9132.

variants of *Salmonella* to the preparation. The Authority also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) On 7 February 2025, the applicant withdrew the application for the authorisation of the preparation of the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 for ornamental birds. Additionally, on 14 April 2025, the applicant withdrew the application for the authorisation of that preparation for use in complementary feed.

(6) In view of the above, the Commission considers that the preparation satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, when used in water for drinking for all poultry species. Accordingly, the use of that preparation should be authorised. It is appropriate to provide for post-market monitoring to address the potential selection and spread of resistant variants of *Salmonella* to the preparation. In addition, the Commission considers that the label of the additive should indicate that the additive cannot be considered as a replacement for the standard hygiene farming conditions. Finally, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) 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
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
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,

For the Commission
The President
Ursula VON DER LEYEN