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EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/8476185/2024 CIS
(POOL/G5/2024/8476185/8476185-EN
CIS.docx)
[...](2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the denial of the renewal of the authorisation of Patent Blue V as a feed
additive for non-food producing animals and repealing Implementing Regulation (EU)
No 643/2013**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the denial of the renewal of the authorisation of Patent Blue V as a feed additive for non-food producing animals and repealing Implementing Regulation (EU) No 643/2013

(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 nutrition¹, 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 an authorisation.
- (2) Patent Blue V was authorised for ten years as a feed additive for non-food producing animals by Commission Implementing Regulation (EU) No 643/2013².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of Patent Blue V as a feed additive for non-food producing animals, requesting that additive to be classified in the additive category ‘sensory additives’ and the functional group ‘colorants, substances that add or restore colour in feedingstuffs’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) As provided for by Article 5(1) of Regulation (EC) No 1831/2003, it is for the applicant of an authorisation of a feed additive to adequately and sufficiently demonstrate, in accordance with the implementing rules referred to in Article 7 of that Regulation, that the conditions for authorisation set out in Article 5(2) and (3) of that Regulation are satisfied. As regards applications for renewal of authorisation, Commission Regulation (EC) No 429/2008³ requires, in particular, that the applicant presents evidence that, in the light of the current scientific knowledge, the additive

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) No 643/2013 of 4 July 2013 concerning the authorisation of Patent Blue V as a feed additive for non-food producing animals and amending Regulation (EC) No 358/2005 (OJ L 186, 5.7.2013, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2013/643/oj).

³ 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, ELI: <http://data.europa.eu/eli/reg/2008/429/oj>).

remains safe under the approved conditions for target species, consumers, workers and the environment.

- (5) The European Food Safety Authority ('the Authority'), in its opinion of 13 March 2024⁴, concluded that the applicant has not provided evidence that the additive currently on the market complies with the existing conditions of authorisation (purity criteria: minimum of 90 % of total colouring matters, calculated as the sodium, calcium or potassium salts). The Authority could not conclude whether Patent Blue V remains safe for the target species due to the non-compliance with the authorised specifications for the use of the additive in feed and the lack of data for the assessment of the potential aneugenicity of the additive.
- (6) By letter of 1 July 2024, the Commission gave the applicant the opportunity to submit supplementary information to address the issues raised in the EFSA opinion. The applicant replied on 20 September 2024 that he had no intention of supplying any additional data for the renewal of the authorisation of Patent Blue V.
- (7) It derives from the Authority's opinion of 13 March 2024 that the applicant has not adequately and sufficiently demonstrated that Patent Blue V remains safe when used as a feed additive for non-food producing animals in the additive category 'sensory additives' and the functional group 'colourants, substances that add or restore colour in feedingstuffs'.
- (8) In view of the above, Patent Blue V does not satisfy the conditions for the renewal of the authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the renewal of the authorisation of that substance as a feed additive belonging to the category 'sensory additives' and the functional group 'colorants, substances that add or restore colour in feedingstuffs' for use for non-food producing animals, should be denied.
- (9) Therefore, the substance Patent Blue V and feed containing it should be withdrawn from the market as soon as possible as far as the use for non-food producing animals is concerned. However, a limited period should be allowed for the withdrawal from the market of the existing stocks of those products, in order to enable operators to comply properly with the withdrawal obligation.
- (10) As a consequence of the denial of the renewal of the authorisation of Patent Blue V as a feed additive for non-food producing animals, Implementing Regulation (EU) No 643/2013 should be repealed.
- (11) 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 renewal of the authorisation

The renewal of the authorisation of Patent Blue V as an additive in animal nutrition, belonging to the category 'sensory additives' and the functional group 'colorants, substances that add or restore colour in feedingstuffs', for use for non-food producing animals, is denied.

⁴ EFSA Journal, 22(4), e8722. <https://doi.org/10.2903/j.efsa.2024.8722>.

Article 2
Repeal of Implementing Regulation (EU) No 643/2013

Implementing Regulation (EC) No 643/2013 is repealed.

Article 3
Withdrawal from the market

1. Existing stocks of the additive referred to in Article 1, which are intended for non-food producing animals, and of premixtures containing it, shall be withdrawn from the market by *[3 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.
2. Feed materials and compound feed which have been produced with the additive or premixtures referred to in paragraph 1 before *[3 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*, and which are intended for non-food producing animals, shall be withdrawn from the market by *[6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.

Article 4
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