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COMMISSION

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

of **XXX**

**concerning the denial of authorisation of a preparation of carvacrol as a feed additive
belonging to the category of zootechnical additives for weaned piglets**

(Text with EEA relevance)

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

of XXX

concerning the denial of authorisation of a preparation of carvacrol as a feed additive belonging to the category of zootechnical additives for weaned piglets

(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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted by Techna France Nutrition for the authorisation of a preparation of carvacrol as a feed additive for weaned piglets, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘other zootechnical additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) As provided for by Article 5(1) of Regulation (EC) No 1831/2003, it is for the applicant for the 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 are satisfied.
- (4) In the preparation of its opinion, the European Food Safety Authority (‘the Authority’) undertook an assessment of the preparation of carvacrol to determine whether it complies with the conditions for authorisation laid down in Article 5 of Regulation (EC) No 1831/2003. In its opinion of 17 March 2020², and again in its follow-up opinion of 31 January 2024³, the Authority could not conclude on the efficacy of the preparation of carvacrol, as only two long term efficacy studies showing significant effects could be considered by the Authority, when Regulation (EC) No 429/2008⁴

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

² EFSA Journal 2020;18(4):6070, <https://doi.org/10.2903/j.efsa.2020.6070>.

³ EFSA Journal. 2024;22:e8639, <https://doi.org/10.2903/j.efsa.2024.8639>.

⁴ 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>.

and the Authority's guidance⁵ required three long term efficacy studies to show significant effects. More in detail, considering all the data provided by the applicant, the Authority concluded that two trials showed positive effects of the preparation of carvacrol in the zootechnical performance of the weaned piglets at the nominal level of 250 mg additive/kg complete feed, while two other studies were not further considered in the efficacy assessment due to high incidence of diarrhoea and high mortality in piglets. The applicant's proposal to remove some data from the analysis of one of those discarded studies was not considered duly justified by the Authority and did not allow for re-considering that study in the efficacy assessment. Consequently, in the absence of a third study showing positive results in the performance of weaned piglets at the proposed use level, the FEEDAP Panel was not in the position to conclude on the efficacy of the additive in weaned piglets.

- (5) By letter of 10 April 2024, the Commission offered to the applicant the opportunity to provide additional information to adequately and sufficiently demonstrate the efficacy of the preparation of carvacrol as a feed additive for weaned piglet. In its replies of 20 and 21 June 2024, the applicant disagreed with the fact that the Authority could not conclude on the efficacy of the preparation of carvacrol, as they considered having provided justified arguments for the Authority to accept an additional efficacy study, and informed the Commission that it was not willing to provide supplementary information nor to withdraw the application.
- (6) Based on the above, the applicant has not adequately and sufficiently demonstrated that the preparation of carvacrol has at least one of the characteristics set out in Article 5(3) of Regulation (EC) No 1831/2003. In particular, and in view of the fact that the applicant requested the preparation to be classified in the category 'zootechnical additives' and the functional group 'other zootechnical additives', the Commission does not consider that the applicant has adequately and sufficiently demonstrated, in accordance with the implementing measures referred to in Article 7 of Regulation (EC) No 1831/2003, that the preparation favourably affects animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, as provided for in Article 5(3)(f) thereof.
- (7) In view of the above, it cannot be considered that the preparation of carvacrol satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that preparation as a feed additive for weaned piglets, belonging to the category 'zootechnical additives' and the functional group 'other zootechnical additives', should be denied.
- (8) 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 a preparation of carvacrol as an additive in animal nutrition belonging to the category 'zootechnical additives' and the functional group 'other zootechnical additives' for use in weaned piglets, is denied.

⁵ In particular, guidance on the assessment of the efficacy of feed additives, adopted on 17 April 2018, EFSA Journal 2018;16(5):5274, <https://doi.org/10.2903/j.efsa.2018.5274>.

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