

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2090
of 25 November 2021
concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species

(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) Titanium dioxide was authorised without a time limit by Directive 70/524/EEC as a colourant additive (colouring agents authorised for colouring foodstuffs by Community rules) for cats and dogs. It was also authorised without a time limit for all animal species, with the exception of cats and dogs, for animal feedingstuffs under certain conditions. That product 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, an application was submitted for the re-evaluation of titanium dioxide as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'sensory additives' and the functional group 'colourants: substances that add or restore colour in feedingstuffs'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') noted in its opinion of 5 May 2021 ⁽³⁾ that it could not conclude on the safety of titanium dioxide for the target species, consumers and environment, given the absence of specific data related to its use as a feed additive and considering that the genotoxicity of particles of titanium dioxide could not be ruled out, raising potential concerns on the safety of the additive for the target species (especially for long-living animals and reproductive animals), consumers and users. In the absence of studies with titanium dioxide, the Authority could not conclude on the assessment of the effects of the additive on eyes and skin. The Authority further noted that titanium dioxide is potentially carcinogenic to workers if inhaled and that, as the genotoxicity of particles of titanium dioxide cannot be ruled out, it should be considered as an additional potential concern to users handling the additive. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The Authority's opinion of 5 May 2021 shows, therefore, that it has not been established that titanium dioxide does not have an adverse effect on animal health, human health or the environment, when used as a feed additive in the functional group 'colourants: substances that add or restore colour in feedingstuffs'.

⁽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⁾ EFSA Journal 2021;19(6):6630.

- (6) The assessment of titanium dioxide thus shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied and accordingly, the authorisation of titanium dioxide as a feed additive belonging to the functional group 'colourants: substances that add or restore colour in feedingstuffs' should be denied.
- (7) Therefore, the feed additive titanium dioxide and feed containing it should be withdrawn from the market as soon as possible. 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.
- (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 titanium dioxide (E 171) as an additive in animal nutrition, in the additive category 'sensory additives' and in the functional group 'colourants: substances that add or restore colour in feedingstuffs', 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 20 March 2022.
2. Feed materials and compound feed which have been produced with the additive or the premixtures referred to in paragraph 1 before 20 March 2022 shall be withdrawn from the market by 20 June 2022.

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, 25 November 2021.

For the Commission
The President
Ursula VON DER LEYEN