

EN
E-006428/2018
Answer given by Mr Andriukaitis
on behalf of the European Commission
(20.2.2019)

In the EU a food additive may be included in the Union list of permitted food additives when, inter alia, it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed¹. The assessment of the safety of food additives in the Union is the responsibility of the European Food Safety Authority (EFSA)².

Titanium dioxide (TiO₂) is a permitted food additive (food colour – E 171) in the Union³. In 2016 EFSA re-evaluated the safety of TiO₂ authorised as a food additive (E 171)⁴ and concluded that E 171 does not raise a concern with respect to genotoxicity, that it is not carcinogenic after oral administration and that the estimated oral exposure to E 171 would not be of concern. EFSA indicated that the exposure to TiO₂ via inhalation was not directly relevant for the safety evaluation of TiO₂ as a food additive and therefore it was not considered in its assessment of E 171. EFSA made recommendations on data needs for further development of the safety assessment of E 171 and improvement of its specifications⁵, which are currently being closely addressed by the Commission⁶. EFSA is expected to adopt an opinion on the proposed amended specifications by 31 July 2019.

EFSA also recently evaluated four new studies on the potential toxicity of E 171⁷. The 2017 study of the French National Institute for Agricultural Research⁸ was one of them. EFSA concluded that these new studies do not modify the conclusions of the 2016 safety assessment. EFSA recommended some additional examinations, which stakeholders have agreed to carry out⁹.

On this basis, the Commission considers that there are currently no grounds to apply precautionary measures regarding the authorisation of E 171 as a food additive.

¹ Regulation (EC) No 1333/2008 on food additives, OJ L 354, 31.12.2008, p. 16–33 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548239394999&uri=CELEX:32008R1333>)

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548239477894&uri=CELEX:32002R0178>)

³ Regulation (EC) No 1333/2008 on food additives, OJ L 354, 31.12.2008, p. 16–33 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548239394999&uri=CELEX:32008R1333>)

⁴ EFSA Panel on Food Additives and Nutrient Sources added to Food, 2016. Scientific Opinion on the re-evaluation of titanium dioxide (E 171) as a food additive. EFSA Journal 2016;14(9):4545 (<https://www.efsa.europa.eu/en/efsajournal/pub/4545>)

⁵ Regulation (EU) No. 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32012R0231>)

⁶ Follow-up of EFSA's scientific opinion on the re-evaluation of titanium dioxide (E 171) as a food additive. Call for scientific and technical data on the permitted food additive titanium dioxide (E 171) (https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en)

⁷ EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018. Evaluation of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171). EFSA Journal 2018;16(7):5366 (<https://www.efsa.europa.eu/en/efsajournal/pub/5366>)

⁸ Bettini, S. et al. Food-grade TiO₂ impairs intestinal and systemic immune homeostasis, initiates preneoplastic lesions and promotes aberrant crypt development in the rat colon. Sci. Rep. 7, 40373; doi: 10.1038/srep40373 (2017).

⁹ New data on reproductive toxicity are expected to be available by the end of 2019.