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TOX/2024/02

Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment.

Third draft statement on the safety of Titanium Dioxide (E171) as a Food Additive

Introduction

1. Titanium dioxide (TiO₂) was an authorised Food Additive (E171) in the EU and currently remains authorised in the UK, under Retained EU Regulation [No. 1333/2008](#) and Retained EU [Regulation No. 231/2012](#). It is used in food as a colour to make food more visually appealing, to give colour to food that would otherwise be colourless, or to restore the original appearance of food. It is commonly used in products such as bakery products, soups, broths, sauces, salad dressings, savoury based sandwich spreads, processed nuts, confectionary, chewing gum, food supplements and cake icing.

2. Titanium dioxide has been the subject of multiple safety evaluations. In 2016, the EFSA ANS (Food Additives and Nutrient Sources) Panel evaluated the safety of E171 TiO₂ and identified several uncertainties in their evaluation included the unspecified identity and characterisation of E171 as it was not determined whether the test material was compliant with the specification of E171 requirements. The EFSA 2016 review determined that E171 TiO₂ consisted mainly of micro-sized TiO₂ particles, with a nano-sized (<100 nm) fraction which was less than 3.2% by mass. Uncertainties around the identity and characterisation of E171 were highlighted, noting that no limits for the particle size of E171 were set. In 2019, the specifications of E171 titanium dioxide were reviewed by the EFSA FAF Panel (Food and Feed). A recommendation for re-assessment of the safety of titanium dioxide was proposed.

3. In the EFSA 2021 Opinion, the EFSA FAF Panel considered that some findings regarding immunotoxicity, inflammation and neurotoxicity with respect to TiO₂ nanoparticles may be indicative of adverse effects. On the basis of the currently

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available evidence and the uncertainties, in particular a concern regarding genotoxicity which could not be resolved, the EFSA Panel concluded that E171 can no longer be considered as safe when used as a food additive.

4. In 2021 the COT published an interim position on titanium dioxide ([COT 2021](#)) capturing the outcomes of the discussions and outlining the next steps. Members were asked to evaluate the EFSA Opinion and comment on whether they agreed with EFSA's conclusions and further guidance on the next steps that should be taken; producing an opinion paper following a review of the new EFSA opinion and the extended one generation reproductive toxicity (EOGRT) study data by both the COT and COM (Committee on Mutagenicity).

5. This draft statement (Annex A) includes the COT conclusions on the following endpoints: ADME, Aberrant Crypt Foci as a marker for Carcinogenicity, Allergenicity, Reproductive and Developmental Toxicity, potential evidence of Immunotoxicity, Inflammation and Neurotoxicity and the derivation of a Health-Based Guidance Value, and a review of genotoxicity endpoints by the COM. Additionally, this statement also includes the titanium dioxide exposure assessment for the UK population.

Questions for the Committee

6. The Committee are asked to consider the following questions:
- i. Are Members content with the layout and structure of the draft statement?
 - ii. Would Members like to see any additional information on studies already included, or consider that other studies should be included?
 - iii. Do Members agree with the layout and structure of the table summarising the studies?
 - iv. Do Members have any other comments?

Secretariat

February 2024