Meeting

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

This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

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.

2. Titanium dioxide has been the subject of multiple safety evaluations. In 2016, the EFSA ANS 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. 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 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 first draft statement (Annex A) includes the COT conclusions on the following endpoints: ADME, Aberrant Crypt Foci, Reproductive and Developmental Toxicity and the derivation of a Health-Based Guidance Value, with amendments required following a further discussion paper on the remaining endpoints discussed in the EFSA 2021 opinion and a review of genotoxicity endpoints by the COM.

Questions for the Committee

6. The Committee are asked to consider the following questions:

- Does the Committee consider that any additional information should be included in the draft statement e.g. detailed summaries of studies?
- What is the Committee's conclusion on the absorption of titanium dioxide? Does the information provided in discussion paper TOX/2023/32 change or add to your conclusions? Is any additional information required in order to reach a final conclusion?
- What are the Committee’s views on the toxicity of nanoparticles and whether a point of departure can be established for the information presented in this draft statement and the discussion paper TOX/2023/32? Does the information provided change the value from 1000 mg/kg bw/day?
- Regarding the studies that were excluded by the EFSA Panel, does the COT want to review any of these studies as part of their own consideration of titanium dioxide?
- Does the Committee require any additional information?
- Do Members have any other comments on the structure of the draft statement?

TOX/2023/33 Annex A

This is a very early draft of the statement on titanium dioxide and as the final form may differ significantly, It has not been published at this time. However, it is anticipated that the next draft of the statement will be published as usual.

Secretariat

July 2023