
The TDMA's observations concerning the EFSA's latest opinion about the safety of E171 – Updated (17 September 2021) with additional information

The European Food Safety Authority (EFSA) [published](#) an opinion on 6 May 2021 concluding that titanium dioxide (TiO₂) can no longer be considered safe for use as the food additive E171. The EFSA could not rule out a concern for genotoxicity from ingestion of E171 based on a perceived gap in data. The Titanium Dioxide Manufacturers Association (TDMA) continues to stand behind the safety of TiO₂ in all intended applications. The TDMA fulfilled all the data requirements requested by the EFSA, all of which showed no adverse effects. The TDMA is addressing the EFSA's opinion by updating its science program to generate further data to confirm the safety of E171.

TDMA's observations concerning the EFSA's Opinion

The EFSA Opinion itself concluded that there was no general toxicity and no organ toxicity, and no effects on reproductive and developmental toxicity. The EFSA did not conclude that E171 is genotoxic, only that there was uncertainty. This view was a reversal of the previous four opinions since 2016, where the EFSA considered E171 was safe. The TDMA would like to share the following key observations:

- 1) The EFSA's opinion is not based on all relevant data concerning the safety of E171. The EFSA has adopted a new risk assessment approach that excludes certain important components of the science dataset for E171 that show no adverse impacts.
- 2) The Opinion differs from the EFSA's previous position that a food additive should be investigated by the dietary route of exposure in a food matrix. The test materials in many studies relied on by the EFSA were intentionally dispersed for testing using high-energy sonication. This does not reflect realistic human exposure to food containing E171. This method of sample preparation appears contrary to EFSA guidance.
- 3) Test materials used in key studies are not representative of E171. E171 is an untreated/non-surface treated pigmentary non-nano grade TiO₂ food ingredient with strict purity requirements, representing less than 1% of TiO₂ produced. The EFSA considered as highly relevant, certain tests that were conducted on materials that are not representative of E171, as it is manufactured, used, and present in foods.
- 4) The Opinion noted several mechanisms by which E171 could possibly be genotoxic. These are highly unlikely because there is a very low potential for systemic absorption and accumulation of E171 as used as a food additive.

Although E171 is not a nanomaterial according to the [EU recommendation](#), in its new Opinion, the EFSA has applied its [2018 EFSA Scientific Committee Guidance on Nanotechnology](#). The TDMA was not been asked to provide any information or studies relating to the application of the new guidance. The TDMA



would have appreciated a more inclusive assessment which would have provided the industry better opportunity to make more new science available to meet the new requirements applied by the EFSA.

European Commission to decide on E171 approval

The TDMA understands that based on the EFSA's latest opinion, the European Commission intends to remove the approval for the use of E171 in food.

In addition and based on the same EFSA Opinion, the EFSA's Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) followed the same conclusion and the TDMA understands that the European Commission is also proposing to deny the authorisation of E 171 as an additive in animal feed.

The TDMA is engaging with the EU Authorities to identify a way forward, and to help answer the concerns raised by the EFSA by providing new science.