
The TDMA's observations concerning the EFSA's latest opinion about the safety of E171

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. This diverges from the previous EFSA opinions which found that E171 as a food additive did not raise concern for genotoxicity.

The Titanium Dioxide Manufacturers Association (TDMA) continues to stand behind the safety of TiO₂ in all intended applications. The TDMA is addressing the EFSA's opinion by updating its science program to generate further data to confirm the safety of E171.

Observations concerning the EFSA's Opinion

The TDMA has been carefully reviewing the EFSA's opinion. It is a complex opinion and it is the first time the 2018 [EFSA Scientific Committee Guidance on Nanotechnology](#) has been applied to the safety assessment of food additives, although E171 is not a nanomaterial according to the [EU recommendation](#).

The TDMA would like to share the following preliminary observations:

- 1) The EFSA opinion is not based on all relevant data concerning the safety of E171. The EFSA has adopted a new risk assessment approach which 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 EFSA did not request any new studies to address any perceived data gaps for E171 on genotoxicity. The TDMA provided extensive new and additional data and information on other risk topics.

The TDMA would have appreciated a more inclusive assessment process given the new risk assessment framework applied by the EFSA. This would have provided the industry better opportunity to make new science available in a timely fashion to meet the new requirements applied by EFSA. The EFSA's new approach to risk assessment could have wide-ranging implications for other substances.

European Commission to decide on E171 approval

The TDMA understands that based on the EFSA's latest opinion, the European Commission intends to propose the removal of E171 from the EU list of approved food additives. The TDMA is engaging with the EU Authorities to identify a way forward and to answer the concerns raised by the EFSA.

