

EuPIA Statement on the EFSA Opinion on the Safety Assessment of Titanium Dioxide (E171) as a Food Additive

On 6th May 2021, the European Food Safety Authority (EFSA) provided an updated safety assessment¹ of the food additive titanium dioxide (E 171) taking into account all new relevant data available to EFSA since the completion of its re-evaluation in 2016. The EFSA evaluation is not linked to the classification of titanium dioxide within chemicals legislation, which is focusing on airborne dust.

Members of EuPIA do not use titanium dioxide as a food additive, but only as a white pigment in printing inks for food contact applications.

In 2013 and 2020, the German Paint and Printing Ink Association VdL commissioned two scientific studies, aimed at investigating the migration behaviour of nano-scale pigment particles from printed food contact materials into food, both during non-direct as well as transient direct contact of the printing ink layer with foodstuff. Both studies also included nano-scale titanium dioxide pigment particles. Both studies confirmed the absence of any migration or set-off of these particles into food. Therefore, a potential oral intake of nanoscale pigment particles (and in particular titanium dioxide pigment particles) resulting from migration from the printing ink layer into food, can be ruled out. The results were presented and discussed with authorities and published in a renowned scientific magazine.²

As part of its continuous improvement strategy, EuPIA carefully examines new scientific findings, including those reported in EFSA opinions. With regard to EFSA's opinion on E171, the relevant EFSA panel concludes that "*based on all the evidence available, a concern for genotoxicity could not be ruled out*".³ This also means, that the panel did not conclude that there is an actual health risk from the use of titanium dioxide as food additive. Following a precautionary approach, and due to "*the many uncertainties, the Panel concluded that E 171 can no longer be considered as safe when used as a food additive.*" This has also been highlighted in the statement of the German Federal Institute for Risk Assessment (BfR) "*In principle, many foods contain ingredients with genotoxic potential. These are very often of natural origin and unavoidable in the daily diet. For some genotoxic substances in food there are findings on adverse health effects in humans. In the case of titanium dioxide, this correlation has not yet been proven by human studies.*"⁴ Since food additives are subject to particular health requirements and put to a high level of scrutiny, a precautionary approach has to be taken.

Following the EFSA Opinion, the European Commission has published a regulation in which food additive E 171 (titanium dioxide) is no longer authorised as a food colour, with a

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/6585>

² M. Henker et al. *Analysis of the migration behaviour from printing ink layers of printed food packaging into the food*, Deutsche Lebensmittel-Rundschau **2013**

M. Henker et al. *Nanoscale pigment particles Investigations on the migration of nanoscale pigment particles from printing ink layers to food during transient direct contact* Deutsche Lebensmittel-Rundschau **2020**

<https://www.eupia.org/key-topics/food-contact-materials/others>

³ The concern is that "*TiO₂ particles have the potential to induce DNA strand breaks and chromosomal damage, but not gene mutations.*"

⁴ <https://www.bfr.bund.de/cm/349/food-additive-titanium-dioxide-e-171-under-scrutiny.pdf>

transitional period of six months.⁵ Although no longer authorised for use in food, titanium dioxide is still listed in Regulation (EC) No 1333/2008 to allow continued use in medicinal products according to Directive 2009/35/EC.

Neither the EFSA Opinion nor Regulation (EU) No 2022/63 affects the legal status of the use of titanium dioxide in printing inks for food contact materials, neither under EU legislation for food contact materials nor under the Swiss Consumer Goods Ordinance (SR 817.023.21). **In conclusion, titanium dioxide can continue to be safely used in printing inks for food contact applications, without risk for the consumer.**

Members of EuPIA are committed to the principle of continuous improvement in consumer safety in the light of any new scientific findings. New evidence such as presented by EFSA, is continuously monitored and assessed and appropriate action is taken if necessary.

About EuPIA

The European Printing Ink Association is the voice of the printing ink industry in Europe. It represents the common interests of about 85 manufacturers of printing inks and varnishes in Europe, which stand for more than 90 % of European ink sales (2019: 910,000 tons; 3.0 billion €). The European Printing Ink Industry employs about 12,000 people. EuPIA operates under the umbrella of CEPE, the European Council of the Paint, Printing Ink and Artists' Colours Industry.

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⁵ Commission regulation (EU) 2022/63 of 14 January 2022, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0063>