EFSA ANNOUNCEMENT



ood additive

afety assessment of titanium dioxide (E171)

E171 no longer considered sa

An Acceptable Daily Intake (ADI) cannot be established for E171.

TiO₂ particles cannot be ruled out.

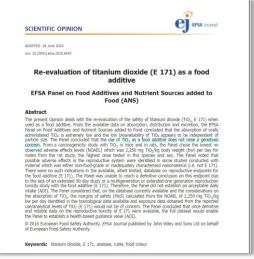
EFSA concluded that a concern for genotoxicity of

- Raises concerns about cancer
- No effects on reproductive and developmental toxicity based on evidence submitted



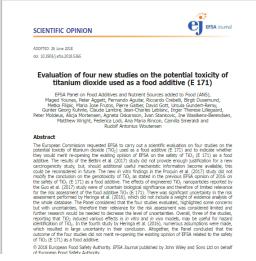
sessment of the food additive titanium dioxide (E 171), for ssion in March 2020.

TIMELINE



EFSA 2016 opinion

"The use of TiO2 as a food additive does not raise a genotoxic concern."



EFSA 2018 opinion

"(...) did not modify the conclusion on the genotoxicity of TiO2 as stated in the previous EFSA opinion of 2016"



EFSA may 2019 opinion

"ANSES recommends
further investigation of in
vivo genotoxicity. EFSA
considers this
recommendation should
be revisited once the
ongoing work on the
physico-chemical
characterisation of the
food additive titanium
dioxide (E 171) is
completed"



EFSA june 2019 opinion

"In particular, the characterisation of titanium dioxide (E 171) does not provide a reason to revise the conclusion on genotoxicity of titanium dioxide (E 171) previously drawn by the ANS Panel."



EFSA 2021 OPINION





A

Basis of the EFSA opinion includes (page 46):

- New information regarding the constituent particle size distribution of E 171
- The updated EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain
- References from the previous ANS Panel opinion (2016)
- Data submitted in the context of the NANOGENOTOX project, 2013
- Publications reported in the OECD dossier (OECD, 2016) and documentation provided by interested business operators (IBOs)

ety assessment of titanium dioxide (E171) as a food additive

EFSA Panel on Food Additives and Flavourings (FAF),
Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fo
Frutos Fernandez, Peter Furst, Ursula Gundert-Remy, Rainer Gurtler, Fr
nia Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina St
Waalkens-Berendsen, Detlef Wolfle, Emanuela Corsini, Francesco Cubac
ima De Groot, Rex FitzGerald, Sara Gunnare, Arno Christian Gutleb, Jan N
icja Mortensen, Agnes Oomen, Aldert Piersma, Veronika Plichta, Beate Ulb
an Loveren, Diane Benford, Margherita Bignami, Claudia Bolognesi, Riccard
ria Dusinska, Francesca Marcon, Elsa Nielsen, Josef Schlatter, Christiane Vler
efania Barmaz, Maria Carfi, Consuelo Civitella, Alessandra Giarola, Ana Maria

sitsa Serafimova, Camilla Smeraldi, Jose Tarazona, Alexandra Tard and Matthe

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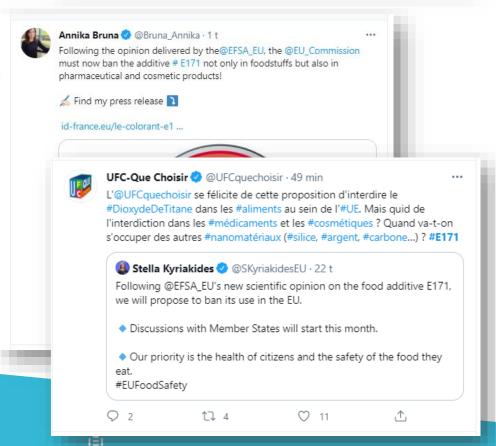
e present opinion deals with an updated safety assessment of the food additive titar (171) based on new relevant scientific evidence considered by the Panel to be reliab ata obtained with TiO2 nanoparticles (NPs) and data from an extended one-generation toxicity (EOGRT) study. Less than 50% of constituent particles by number in E 171 have external dimension < 100 nm. In addition, the Panel noted that constituent particle amounted to less than 1% of particles by number. The Panel therefore considered that TiO, NPs < 30 nm were of limited relevance to the safety assessment of E 171. The Pan that although gastrointestinal absorption of TiO2 particles is low, they may accumulate Studies on general and organ toxicity did not indicate adverse effects with either E 171 up 1,000 mg/kg body weight (bw) per day or with TiO, NPs (> 30 nm) up to the highest do 100 mg/kg bw per day. No effects on reproductive and developmental toxicity were obser dose of 1,000 mg E 171/kg bw per day, the highest dose tested in the EOGRT stud observations of potential immunotoxicity and inflammation with E 171 and potential neuro TiO2 NPs, together with the potential induction of aberrant crypt foci with E 171, may indi effects. With respect to genotoxicity, the Panel concluded that TiO2 particles have the nduce DNA strand breaks and chromosomal damage, but not gene mutations. No clea ras observed between the physico-chemical properties of TiO, particles and the outco vitro or in vivo genotoxicity assays. A concern for genotoxicity of TiO, particles that ma-E 171 could therefore not be ruled out. Several modes of action for the genotoxicity ma allel and the relative contributions of different molecular mechanisms elicited by TiO2 lown. There was uncertainty as to whether a threshold mode of action could be on, a cut-off value for TiO-, particle size with respect to genotoxicity could not be in iately designed study was available to investigate the potential carcinogenic effe sed on all the evidence available, a concern for genotoxicity could not be ruled ou uncertainties, the Panel concluded that E 171 can no longer be considered as

> topean Food Safety Authority. EFSA Journal published by John Wiley and Sons Li Food Safety Authority.

tanium dioxide, E 171, CAS No 13463-67-7

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MEDIA/POLITICAL REACITON

Political

- Commissioner for Health, Stella Kyrakides, <u>tweeted</u> that the Commission will ban the use of E171 in the EU and the discussions will start with the Member States this month.
- German Agriculture Minister Julia Klöckner said in a <u>statement</u> that she asked Commission to move forward with ban
- ANSES welcomed conclusions of EFSA French Government still to react

Media/social media

- Story was reported by tier 1 EU media in major markets including the Guardian, El Pais, Zeit, Le Monde etc.
- Stories mostly relay EFSA conclusion and political reactions across Europe
- High volume of negative reactions on social with strong focus from NGOs to push for immediate political action

WHAT NEXT

- The Commissioner will not backtrack after promising a ban of E171 in food on the record
- Given France and Germany support combined with a negative EFSA opinion, it is difficult to change the situation in SCOPAFF
- The ban would meet the European Parliament's request in its objection to the revised E171 specification last autumn
- New court judgement makes clear under the precautionary principle that measures may be taken without an exhaustive risk assessment
 - See Case C-499/18 P, Bayer CropScience AG v. Commission

