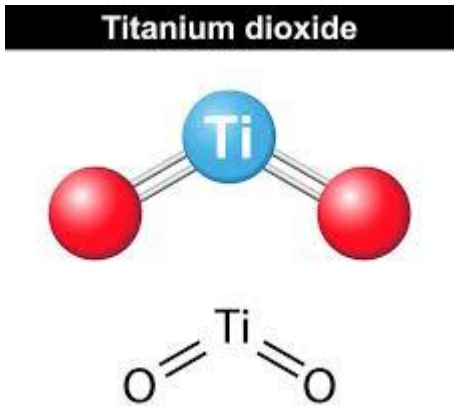

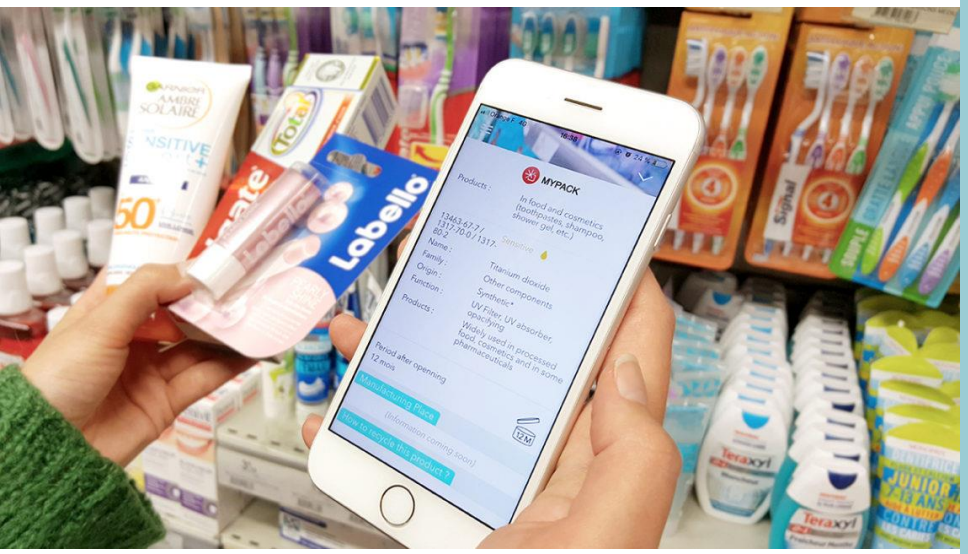

Netherlands Food and Consumer
Product Safety Authority
Ministry of Agriculture,
Nature and Food Quality

Opinion on possible health effects of the food additive titanium dioxide (E171)

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Background

Titanium dioxide (TiO_2): white colouring agent with many applications, including use in foods, e.g. as food additive E171.

IARC: TiO_2 is possibly carcinogenic to humans after inhalation

ECHA opinion (2017): TiO_2 to be classified as cat. 2 carc. after inhalation

EFSA (2016): no human health effects upon (present) oral exposure

Scientific literature (recent): reports on harmful effects of E171 in laboratory animals

EFSA (2018): newly published data insufficient to amend previously risk assessment, however, recommendation for further research

BuRO (2018, in parallel to EFSA) organized workshop on concern over intestinal cancer promotion by E171

ANSES report (2019) is in line with this notion

BuRO Workshop on E171, July 5-6, 2018, NL

Organized by the Office of Risk Assessment and Research (BuRO) from the Netherlands Food and Consumer Safety Authority

Participants from universities (Mexico, The Netherlands), clinic (Switzerland), national European institutes of public health (Denmark, France, Germany, Norway, The Netherlands, United Kingdom), and EFSA

Aims of the workshop

1. to present an overview of studies on the biological effects of E171 and the potential health effects of food grade TiO_2, and in particular;
2. to appraise the quality of in vivo studies available in terms of the conclusions made;
3. to conclude whether these studies point to mechanisms that may underlie effects of E171;
4. to evaluate whether the data provide information on a dose-effect relationship;
5. to conclude whether the studies give rise to a concern for safety in the population consuming E171;
6. to decide if the current data would be sufficient for a re-assessment of the risk of E171; and
7. if not, to identify data gaps, in particular what is missing for an appropriate risk assessment for regulatory purposes.

Recommendations BuRO

to the Dutch Minister for Medical Care (Public Health)

1. Engage in discussion with the food producers to reduce exposure to E171 and/or TiO_2.
2. Examine the contribution of E171 or titanium dioxide in other products, such as medicines, to consumer exposure, especially in people with increased intestinal permeability.
3. In view of the possible adverse health effects of ingesting E171 and in consultation with EFSA, the trade associations intend to conduct additional laboratory animal research –an Extended One-Generation Reproductive Toxicity Study (EORGTS) –in which cohorts are included for reprotoxicological and immunotoxicological tests. BuRO primarily recommends encouraging this research to also include analyses of parameters that are important for the development of colon cancer, and for which indications were found in the aforementioned studies that they are influenced by the intake of E171.
4. Study the effects found in laboratory animals and in *in vitro* studies in humans. Even though it is not possible to study colon cancer as a direct result of exposure to E171 in intervention research in humans, it is possible to study intermediary parameters that are associated with colon cancer and for which it was proved in laboratory animals and *in vitro* that they are influenced by E171. The results of such a study will provide insight into the relevance of the laboratory animal and *in vitro* studies. A valid risk assessment will not be possible as long as these studies are not completed.

Timelines

- June 11, 2019:

Formal draft sent to Ministry

- July 23, 2019:

Formal date of Opinion

- August 20, 2019:

Formal date of publication on the website