



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels, 103.05.2019
SANTE.E2/ (2019)3212981

Ares(2019)2955830

Dear Dr Url,

Subject: Request for urgent scientific and technical assistance as regards the review on the risks related to the exposure to the food additive titanium dioxide (E 171) performed by ANSES

On 15 April 2019, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) published a review¹ of the risks related to the ingestion of the food additive titanium dioxide (E 171) taking into account the most recent scientific studies available.

In accordance with Article 31 of Regulation (EC) No 178/2002, the European Commission requests the European Food Safety Authority (EFSA) to provide by 10 May 2019 a scientific statement assessing the review performed by ANSES, including the recommendations made, to consider whether:

- (i) it includes any new and major findings showing that titanium dioxide (E 171), when used as a food additive, is of safety concern and thus it overrules the conclusions made in the scientific opinion re-evaluating safety of titanium dioxide (E 171) as a food additive (2016)² or in the evaluation of four studies on the potential toxicity of titanium dioxide used as a food additive (E 171) (2018)³;
- (ii) it identifies further uncertainties which are worth addressing in addition to the aspects for which the follow up work is currently ongoing⁴.

You will find attached the background and the terms of reference for this request.

¹ <https://www.anses.fr/en/content/food-additive-e171-anses-reiterates-its-recommendations-consumer-safety>

² <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4545/full>

³ <http://www.efsa.europa.eu/en/efsajournal/pub/5366>

⁴ https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_reeval_call_20170130_e171_data.pdf

Dr Bernhard Url
Executive Director
European Food Safety Authority
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My services remain at your disposal for further information. On this matter, you can contact [REDACTED] and [REDACTED], who are responsible for this dossier in Unit E2 Food Processing Technologies and Novel Foods, and [REDACTED], who is the relevant contact point in Unit D1, which is in charge of relations with EFSA. Their respective phone and e-mail addresses are indicated below.

Yours sincerely,

[REDACTED]

Anne Bucher

Contact persons:

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Annex: Request for urgent scientific and technical assistance as regards the review on the risks related to the exposure to the food additive titanium dioxide (E 171) performed by ANSES

c.c.: Mr M. Hudson, Ms S. Jülicher, [REDACTED]
[REDACTED] (SANTE)

ANNEX

Request for urgent scientific and technical assistance as regards the review on the risks related to the exposure to the food additive titanium dioxide (E 171) performed by ANSES

Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives⁵. Only food additives that are included in the Union list, in particular in Annex II to that Regulation, may be placed on the market and used in foods under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012⁶.

Titanium dioxide is authorised for use as a food additive (food colour) in the Union. Since titanium dioxide (E 171) was permitted in the Union before 20 January 2009, it belongs to the group of food additives which are subject to a new risk assessment by the European Food Safety Authority (EFSA), according to Commission Regulation (EU) No 257/2010⁷, and in line with the provisions of Regulation (EC) No 1333/2008.

The re-evaluation of titanium dioxide as a food additive (E171) was completed by EFSA in June 2016 and a scientific opinion was published in September 2016⁸. In that opinion, EFSA concluded, on the basis of the available evidence, that titanium dioxide used as a food additive (E 171) does not raise a concern with respect to genotoxicity, it is not carcinogenic after oral administration and exposure from the reported use/analytical levels would not be of concern. However, some recommendations were made, which are being followed up by the European Commission⁹, to address data gaps highlighted in the scientific opinion.

In April 2017, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) published an opinion on dietary exposure to nanoparticles of titanium dioxide¹⁰ assessing, in particular, the study of Bettini et al. (2017) and concluded that the data do not question the risk assessment performed by EFSA and cannot be used before having been confirmed by additional studies.

In March 2018, the Commission requested EFSA to evaluate four new studies describing a potential adverse health effect of titanium dioxide used as a food additive. The EFSA opinion completed in June 2018 concluded that the outcome of the four studies did not merit re-opening the existing opinion of EFSA related to the safety of titanium dioxide (E 171) as a food additive¹¹.

⁵ OJ L 354, 31.12.2008, p. 16.

⁶ OJ L 83, 22.3.2012, p. 1.

⁷ OJ L 80, 26.3.2010, p. 19.

⁸ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4545/full>

⁹ https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

¹⁰ <https://www.anses.fr/fr/system/files/ERCA2017SA0020.pdf>

¹¹ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5366>

On 15 April 2019, ANSES published a review of the risks related to the ingestion of the food additive titanium dioxide (E 171)¹² taking into account the most recent scientific studies available and referring to its opinion of 2017.

The legislation on food additives envisages that food additives should be kept under continuous observation and be re-evaluated whenever necessary in the light of new scientific information. Therefore, it is appropriate to ask EFSA for a scientific assistance to scrutinise the review of new scientific information made by ANSES.

Terms of reference

In accordance with Article 31 of Regulation (EC) No 178/2002¹³, the European Commission requests the European Food Safety Authority (EFSA) to provide a scientific statement in relation to the review performed by ANSES on titanium dioxide (E 171).

In particular, EFSA is requested to consider whether the review made by ANSES:

(i) includes any new and major findings showing that titanium dioxide (E 171), when used as a food additive, is of safety concern and thus overrules the conclusions made in the scientific opinion re-evaluating safety of titanium dioxide (E 171) as a food additive (2016) or in the evaluation of four studies on the potential toxicity of titanium dioxide used as a food additive (E 171) (2018);

(ii) identifies further uncertainties which are worth addressing in addition to the aspects for which the follow up work is currently ongoing.

¹² <https://www.anses.fr/en/content/food-additive-e171-anses-reiterates-its-recommendations-consumer-safety>

¹³ OJ L 31, 1.2.2002, p. 1.