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**SUMMARY REPORT OF THE
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED
HELD IN BRUSSELS ON 13 MAY 2019
(Section Novel Food and Toxicological Safety of the Food Chain)**

CIRCABC Link: <https://circabc.europa.eu/w/browse/fed94c24-fd8d-4264-9b16-32ad2584e731>

A.01 Exchange of views on the emergency measure regarding titanium dioxide when used as a food additive (E171), as notified by France on 26/04/2019 according to Article 54 of Regulation (EC) No 178/2002.

France presented an Order (ECOC1911549A) of 17 April 2019 suspending the placing on the market of foodstuffs containing the food additive titanium dioxide (E 171) as of 1 January 2020, for one year. The Order, which was notified to the European Commission on 26 April 2019, was adopted pursuant Article 54 of Regulation (EC) No 178/2002 and Article L. 521-17 of the French Consumer Code, and is based on a new opinion of the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) on the risks associated with ingesting the food additive E171 dated 12 April 2019.

France explained the reasoning behind this decision. This Order was preceded by a note from the French authorities sent to the European Commission on 15 February 2018, which requested the adoption of interim protective measures provided for by Article 53 of Regulation (EC) No 178/2002. Such protective measures are to be taken when it is evident that food or feed originating in the Union or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment. Since the scientific opinions on the safety of titanium dioxide as a food additive (E 171) issued by the European Food Safety Authority (EFSA) in 2016 and 2018 concluded that the current use of titanium dioxide as a food additive is not of safety concern, no such measures were adopted.

In accordance with Article 54 of Regulation (EC) No 178/2002, where a Member State officially informs the Commission of the need to take emergency measures and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. These measures may be maintained until Union measures are adopted.

ANSES was invited to present its opinion, dated 12 April 2019, on the risks associated with ingesting the food additive E171. ANSES explained that it carried out a review of literature on the oral toxicity of titanium dioxide published since the previous ANSES opinion issued in 2017. ANSES considered 25 new publications, some of which identify new findings on potential effects of titanium dioxide. However, none of the new publications confirms or rules out the effects reported by Bettini *et al.* in 2017 with respect to potential tumour-promoting effects of titanium

dioxide. ANSES concluded that the new findings identified do not eliminate the uncertainties regarding the safety of titanium dioxide as a food additive (E 171) and recommended that E 171 is precisely characterised in physicochemical terms and that new data are generated to allow reaching a conclusion on the various effects observed, in particular on genotoxicity, carcinogenicity and reproductive toxicity. Furthermore, ANSES recommended a reassessment of the conditions for authorisation of E 171 with respect to technological need and benefits for consumers.

The Commission requested EFSA on 3 May 2019 to provide urgent scientific and technical assistance regarding this ANSES opinion. In particular, EFSA was requested to indicate whether the ANSES opinion includes any new and major findings showing that titanium dioxide (E171), when used as a food additive, is of safety concern and thus overrules the conclusions made in the two previous EFSA scientific opinions on E 171 from 2016 and 2018. The Commission invited EFSA to present its statement on the review of the risks related to the exposure to the food additive titanium dioxide (E 171) performed by ANSES (the EFSA statement was published on 13 May 2019).

In its presentation, EFSA reported that it considers that the ANSES opinion does not identify any major new findings that would overrule the conclusions made in the previous two scientific opinions on the safety of titanium dioxide as a food additive (E171) issued in 2016 and 2018. According to EFSA, the ANSES opinion reiterates the previously identified uncertainties and data gaps, which are currently being addressed in the context of the follow-up activities originating from the previous EFSA evaluations and their recommendations. In addition to the aspects for which the follow-up work is currently ongoing, 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 (E171) is completed. EFSA's presentation also provided an overview on its ongoing work on E 171 (opinion on physico-chemical characterisation of E 171, expected to be adopted by the end of June 2019) as well as the additional toxicological data which is currently being generated (in particular with respect to reproductive toxicity, including developmental neurotoxicity and developmental immunotoxicity, and carcinogenicity).

After the presentations by France, ANSES and EFSA, the Member States representatives had the opportunity to exchange views on the French emergency measure regarding E 171. Eighteen Member States took the floor. All of them highlighted the importance of keeping harmonised rules for food additives in the Union and therefore the relevance of reaching a common position with respect to the French measure on E 171. They also indicated that the advice of EFSA (the risk assessor) on the safety of titanium dioxide as a food additive should serve as a reference.

The Commission stressed that ensuring that permitted food additives are safe, in line with the provisions of Regulation (EC) No 1333/2008, remains its priority. Therefore, the Commission will give the appropriate follow-up to any new recommendation made by EFSA on E 171, as it has done in the past. Once EFSA issues its opinion on the physico-chemical characteristics of titanium dioxide as a food additive (E 171), the Commission will work on reviewing the specifications of E 171 in Regulation (EU) No 231/2012.

The Commission explained that the input provided by EFSA and the Member States will feed into the reflection concerning the further handling of the French notification by the Commission.