

Brussels, 29 April 2019

To:

[REDACTED]

[REDACTED]

DG SANTE

E.2. Food processing technologies and novel foods

European Commission

Rue de la Loi / Wetstraat 200

1049 Brussels

**French ban on the placing on the market of all foodstuffs containing the food additive Titanium dioxide (TiO<sub>2</sub>, E 171)**

Dear [REDACTED],

Following our letters of 26 October 2018 and of 1 February 2019, we write to you to reiterate our concerns about the intention of French authorities to adopt a one-year national ban on the placing on the market of all foodstuffs containing the permitted food additive Titanium dioxide (TiO<sub>2</sub>, E171) as of 1 January 2020<sup>1</sup>.

The use of TiO<sub>2</sub> is permitted in several food categories, by Regulation (EC) No 1333/2008. Many food and drink producers and food supplements producers use this additive in the permitted food categories, and it is technically challenging to replace it with a suitable alternative, given its functionalities.

The French authorities based their decision on an inconclusive opinion from April 2019 from their ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, that reviewed the conclusions of several studies published since 2017 on the safety of TiO<sub>2</sub> in food<sup>2</sup>. This decision seems to ignore the Scientific Opinion of the European Food Safety Authority (EFSA) on the safety of TiO<sub>2</sub> in food, which resulted from the latest re-evaluation in 2016, and where EFSA concluded that "the margins of safety [...] of TiO<sub>2</sub> (E 171) [...] would not be of concern".

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<sup>1</sup> Arrêté du 17 avril 2019 portant suspension de la mise sur le marché des denrées contenant l'additif E 171 (dioxyde de titane - TiO<sub>2</sub>) <https://www.legifrance.gouv.fr/eli/arrete/2019/4/17/ECOC1911549A/jo/texte>

<sup>2</sup> AVIS de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif aux risques liés à l'ingestion de l'additif alimentaire E171 <https://www.anses.fr/en/system/files/ERCA2019SA0036.pdf>

EFSA also evaluated the initial (2017) study on which the precautionary measure of the French administration is based, together with three other studies published after the 2016 re-evaluation by EFSA, and concluded that the outcome of the four studies did not merit re-opening the existing opinion of EFSA related to the safety of TiO<sub>2</sub> (E 171) as a food additive.” (4 July 2018)

In its opinion, EFSA recommended gathering additional scientific and technical data for addressing the issues identified by the Panel, linked to the specifications for TiO<sub>2</sub> and the establishment of an ADI. In line with these recommendations, and as Commissioner Andriukaitis mentioned in his letter of 20 February (Ref. Ares(2019)1050290), the specifications of TiO<sub>2</sub> will be updated to include particle size parameters and additional research on the safety is being carried out, to decrease uncertainties and complete the available knowledge for TiO<sub>2</sub>. According to the answer given by Commissioner Andriukaitis to the question from MEP Caputo on E 171 (Ref. E-006428-18), EFSA is expected to adopt an opinion on the proposed amended specifications by 31 July 2019. The answer confirms that on this basis, the Commission considers that there are currently no grounds to apply precautionary measures regarding the authorisation of E 171 as a food additive.

EFSA also recommended that an extended 90-day study or a multigeneration or extended-one generation reproduction toxicity study according to the current OECD guidelines could be considered. We understand that this work is currently underway, with results expected in the course of 2020.

ANSES' scientific conclusions from April 2019 simply concurred with EFSA's previous recommendations that additional studies should be performed to address gaps identified in the risk assessment. To this end the European Commission has launched a call for data, **which the manufacturers of E 171 have committed to provide shortly, on the basis of on-going studies**<sup>3</sup>.

As the use of additives in foodstuffs is subject to harmonised EU legislation, it is our opinion that any potential modification of the authorisation of the use of TiO<sub>2</sub> in food in the EU should be based on the analysis of the above-mentioned data, once published by EFSA. Subsequently, any risk management measures should be based on the outcome of EFSA's risk assessment.

It is our view, therefore, that there is no legal basis for France to unilaterally suspend the use of this additive, **which would set an important precedent undermining the fundamentals of EU harmonized law and the Internal Market and precluding the value of the studies that are currently underway.**

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<sup>3</sup> See the confirmation of on-going studies and expected delivery dates by the Titanium Dioxide Manufacturers Association (TDMA), dated 19 April 2019: <https://tdma.info/press-release/>

We therefore ask the Commission to **firmly object to this national legislation.**

Thanking you in advance for taking these remarks into consideration, we are available for a meeting to discuss these developments in more detail.

Yours sincerely,



On behalf of  
Food Supplements Europe  
FoodDrinkEurope  
EU Specialty Food Ingredients