EUROPEAN COMMISSION



DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

03.06.2019

Brussels, SANTE.E2A (2019)3803865 Ares(2019)3568373

Dear

Subject: Your letter – Civil society organisations demand the removal of E171 from the EU list of permitted food additives

Many thanks for the letter of 3 May 2019, that you sent with eight additional civil society organisations, requesting the removal of titanium dioxide (E 171) from the EU list of permitted food additives. Vice-President Katainen asked me to reply on his behalf.

I would like to reassure you that the European Commission takes the safety of food consumed by European citizens very seriously. Therefore, the Commission is closely following any new scientific information on the safety of titanium dioxide as a food additive (E 171), with the support of the European Food Safety Authority (EFSA), to make sure that this substance meets the safety requirements laid down in Regulation (EC) No 1333/2008¹.

EFSA re-evaluated the safety of titanium dioxide as a food additive (E 171) in 2016² and concluded that the current exposure to titanium dioxide from its food additive use was safe.

In 2018³ EFSA evaluated four new studies on the potential toxicity of titanium dioxide used as a food additive, which were mentioned by the French authorities as a justification for their request to the Commission of 15 February 2018 to take measures suspending the placing on the market or use of the food additive titanium dioxide (E171) in line with Article 53 of Regulation (EC) No 178/2002⁴. After analysing the studies, EFSA concluded that they did not require reopening the 2016 opinion of EFSA related to the safety of titanium dioxide as a food additive.

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¹ https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R1333

² https://www.efsa.europa.eu/en/efsajournal/pub/4545

³ https://www.efsa.europa.eu/en/efsajournal/pub/5366

⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002R0178

Upon the receipt of a notification from the French authorities of an Order (ECOC1911549A)⁵ of 17 April 2019 suspending for one year the placing on the market of foodstuffs containing the food additive titanium dioxide (E 171), as of 1 January 2020, the Commission requested EFSA to provide urgent scientific and technical assistance regarding 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 E 171⁶, dated 12 April 2019. This new opinion serves as the basis for the French emergency measure. On 13 May 2019 EFSA issued a statement⁷ indicating that the ANSES opinion does not identify any major new findings that would warrant a change in the conclusions in the 2016 and 2018 EFSA opinions on the safety of titanium dioxide as a food additive (E 171).

With respect to the French Order suspending the placing on the market of foodstuffs containing the food additive titanium dioxide (E 171), the Commission organised an extraordinary meeting of the Standing Committee on Plants, Animals, Food and Feed (Section Novel Food and Toxicological Safety of the Food Chain) on 13 May 2019, to exchange views on that measure. In that meeting, both ANSES and EFSA presented their latest assessments of the safety of titanium dioxide as a food additive (E 171). The eighteen Member States which took the floor 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 the reference. The Commission explained that the input provided by EFSA and the Member States will feed into the reflection concerning the further handling of the measure notified by France to the Commission.

In its assessments of the safety of E 171, EFSA has identified certain uncertainties and data gaps. These have been quickly followed up by the European Commission by requesting business operators to provide the needed data⁸ as soon as possible and mandating EFSA to evaluate this information. For example, EFSA is currently assessing data provided by business operators on the physicochemical characterisation of titanium dioxide used as a food additive (E 171), in particular with respect to particle size distribution. EFSA's scientific opinion on this issue, which is expected to be adopted by the end of June 2019, will be used to amend the EU specifications for titanium dioxide (E 171) as laid down in Commission Regulation (EU) No 231/2012⁹ so that these better define which titanium dioxide can be used as food additive.

It should be also noted that Regulation (EC) No 1333/2008 sets conditions for inclusion of food additives in the Union list, which go beyond the above-mentioned safety requirements. General conditions for inclusion in the Union food additive lists are laid down in Article 6. In addition, Article 8 lays down special conditions for food colours, such as E 171.

⁵ https://www.legifrance.gouv.fr/jo pdf.do?id=JORFTEXT000038410047

⁶ https://www.anses.fr/fr/system/files/ERCA2019SA0036.pdf

⁷ https://www.efsa.europa.eu/en/efsajournal/pub/5714

⁸ https://ec.europa.eu/food/safety/food improvement agents/additives/re-evaluation en

⁹ https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32012R0231

Since I would like to better understand your concerns about the use of titanium dioxide as a food additive (E 171), I would be extremely interested to meet you and the other civil society organisations co-signing your letter as soon as you are available. If you agree with this proposal, I would like to ask you to get in touch with my office to arrange for such a meeting.

Yours sincerely,

Anne Bucher