



Vice-President Jyrki Katainen  
European Commission  
Rue de la Loi 200  
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Brussels, 3<sup>rd</sup> May 2019

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

Dear Vice-President,

We are writing regarding the notification by France of a decree suspending the placing on the French market of foodstuffs containing the food additive titanium dioxide (E171) as of January 2020 over concerns about its safety for consumers. The measure will be examined at a meeting of the Standing Committee on Plants, Animals, Food and Feed taking place on 13 May 2019.

Because all Europeans deserve the same high level of protection, **the undersigned organisations call on the European Commission to follow suit and put forward a legislative proposal removing E171 from the EU list of permitted food additives.**

In the meantime, **we urge you not to raise any objections or initiate any legal proceedings against the French measure.** Ahead of the European elections, any move to challenge or delay the French measure would risk sending the wrong signal to EU citizens, who expect the EU to put their health and safety first.

Indeed, the French decree is based on the precautionary principle after the French food safety agency, ANSES recently confirmed that significant uncertainties remain as to the health effects for consumers of the additive E171.

According to EU legislation, a food additive may only be authorised if its use is safe, technologically justified, and if it does not mislead, but on the contrary benefits, the consumer: **E171 meets none of these conditions.**

- **Safety:** As clearly emerged from the ANSES report, scientific uncertainties and data gaps remain, which do not allow lifting concerns over the potential toxicity of E171 for consumers. The 2016 opinion by the European Food Safety Authority, EFSA on E171 also pointed at a lack of data hindering the full safety risk assessment of the additive.

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The European Commission should therefore **apply the precautionary principle** and propose to remove E171 from the EU list of permitted food additives. It is remarkable that these uncertainties partly result from manufacturers' failure to provide the necessary data to conduct the risk assessment. The '**no data, no market**' approach, which prevails in the chemicals sector under the REACH legislation, should also apply to regulated substances in the food area, such as food additives, to prove their safety.

- Technological need: There is no convincing technological need for the use of E171. Many food manufacturers and retailers operating on the French market have already removed E171 from their products or are in the process of phasing it out. The move is even spreading beyond Europe, with some multinational companies having committed to remove E171 from their food portfolio.
- Benefits and advantages for the consumer: E171 is only used for aesthetic purposes. It has no nutritional value, nor does it fulfil any beneficial technological function in food (e.g. extending shelf life).

**We therefore urge the European Commission to protect the health of European consumers and propose to ban the use of E171 in food.**

Further detailed information on the reasons behind our request is available as an annex to this letter. We remain at your disposal to discuss this matter with your services.

Yours sincerely,

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BEUC

Carroll Muffet  
Director  
Center for  
International  
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Justin Wilkes  
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Supporting national organisations:

1. Agir pour l'Environnement (FR)
2. Altroconsumo (IT)
3. Bio Consom'acteurs (FR)
4. Bund für Umwelt und Naturschutz Deutschland (BUND) (DE)
5. Comité pour le développement durable en santé (C2DS) (FR)
6. Consommation Logement Cadre de vie (CLCV) (FR)
7. Consumentenbond (NL)
8. EKPIZO (EL)
9. Fédération romande des consommateurs (FRC) (CH)
10. foodwatch France (FR)
11. Forbrugerrådet Tænk (DK)

12. France Nature Environnement (FNE) (FR)
13. Générations Cobayes (FR)
14. Générations futures (FR)
15. Greenpeace (FR)
16. Institut national de la Consommation (INC) – 60 Millions de consommateurs (FR)
17. KEPKA (EL)
18. Léo Lagrange Défense des Consommateurs (FR)
19. Ligue contre le cancer (FR)
20. Mouvement de l'Agriculture Bio-Dynamique (MABD) (FR)
21. Miramap (FR)
22. Réseau Environnement Santé (RES) (FR)
23. Sciences citoyennes (FR)
24. SEPANSO (FR)
25. Terre et Humanisme (FR)
26. Test-Achats/Test-Aankoop (BE)
27. UFC-Que Choisir (FR)
28. Union Nationale des Associations Familiales (UNAF) (FR)
29. Yuka (FR)
30. Zveza Potrošnikov Slovenije (ZPS) (SI)

**C.c.** Arūnas Vinčiūnas, Head of Cabinet to the Health & Food Safety Commissioner (DG SANTE); Anne Bucher, Director-General (DG SANTE); Sabine Juelicher, Director of Directorate E (DG SANTE); Bruno Gautrais, Head of Unit E2 (DG SANTE); Jiri Sochor, team Leader Food Improvement Agents

## ANNEX

On 17 April 2019, France announced<sup>1</sup> that it had adopted a decree to suspend the placing on the French market of foodstuffs containing the food additive titanium dioxide (TiO<sub>2</sub> - E 171) as of 1<sup>st</sup> January 2020. The decree was published<sup>2</sup> in the French Official Journal on 25 April 2019 and was subsequently notified to the European Commission. The measure will be examined at a meeting of the Standing Committee on Plants, Animals, Food and Feed taking place on 13 May 2019.

This decree by the French government, which is based on the application of the precautionary principle, follows the publication by the French agency for food, environmental and occupational health, ANSES of a report<sup>3</sup> (in French only) which analysed 25 new studies on E 171's toxicity published since 2017. The report concludes that significant scientific uncertainties persist as to the health effects for consumers of exposure to TiO<sub>2</sub> via ingestion.

TiO<sub>2</sub> is found in many everyday products, as pigment-grade particles for use as whitening and opacifying agents in paints, cosmetics or food, where it is referred to as E171. It is widely used in a range of foodstuffs, including confectionery, bakery and sauces. E 171 consists in a mixture of particles of different sizes, including a nanosized fraction. Because of their extremely small size, nanoparticles can pass through protective body barriers and get into the liver, lungs or intestines. They can exhibit different properties compared to their larger sized versions, and as such they can also raise new risks to health and the environment.

Human oral exposure to TiO<sub>2</sub> is estimated to range between 0.2 and 0.4 mg per kg of body weight in infants and the elderly, and up to 5.5 –10.4 mg per kg b.w. in children, depending on the exposure scenario. TiO<sub>2</sub> intake occurs mostly *via* the ingestion of candy, coffee creamer and sauces, and toothpaste by young children<sup>4</sup>.

Tests carried out on the French market by consumer and environmental groups have unveiled the presence of unlabelled nanoparticles of E 171 in many popular foodstuffs such as sweets, chewing-gums and cakes frequently consumed by children and other vulnerable populations<sup>5</sup>.

According to EU Regulation (EC) No 1333/2008 on food additives, a food additive may only be authorised if its use is safe, technologically justified, and if it does not mislead, but on the contrary benefits, the consumer: E 171 meets none of these conditions.

- **Safety:** In 2016, the European Food Safety Agency (EFSA) published its scientific opinion re-evaluation the safety of E 171<sup>6</sup>. While it concluded that available data did not suggest any immediate health concern, EFSA highlighted some data gaps and uncertainties hindering the full safety re-evaluation of the additive. In particular, the expert panel in charge of the re-evaluation could not reach definitive conclusions on the potential reproductive toxicity of E 171, and for that reason did not establish a safe intake level (Acceptable Daily Intake) for the additive. The Commission subsequently requested industry<sup>7</sup> to provide additional data and information, notably on the particle size and particle size distribution of E 171 because of their potential toxicological importance.

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<sup>1</sup> [Press release](#) issued by the French Ministry of Ecological Transition.

<sup>2</sup> Decree from the 17<sup>th</sup> of April relating to the suspension of the placing on the market of foodstuffs containing the food additive E 171 (titanium dioxide) [published](#) in the French Official Journal on the 25<sup>th</sup> of April.

<sup>3</sup> ANSES [scientific opinion](#) on the health risks associated with E 171 ingestion published on 15 April 2019.

<sup>4</sup> Dorier M *et al.* The food additive E171 and titanium dioxide nanoparticles indirectly alter the homeostasis of human intestinal epithelial cells in vitro. *Environ. Sci.: Nano*, Advance Article, 2019.

<sup>5</sup> Tests carried out by [Agir Pour l'Environnement](#), [60 millions de consommateurs](#) and [UFC – Que Choisir](#).

<sup>6</sup> EFSA safety [re-evaluation](#) of titanium dioxide (E 171) as a food additive.

<sup>7</sup> Additional request for data published on DG SANTE [website](#).

However, new studies became available, indicating several potential health risks (incl. genotoxicity and carcinogenicity) for consumers from oral exposure to E 171. Notably, a study by the French National Institute for Agricultural Research<sup>8</sup> showed for the first time that E171 crosses the intestinal barrier in animals and reaches other parts of the body. Immune system disorders linked to the absorption of the nanoscale fraction of E171 particles were observed. The researchers also showed that chronic oral exposure to the additive spontaneously induced precancerous lesions in rats, while acknowledging that more evidence was needed to extrapolate the results to humans.

In March 2018, the Commission mandated EFSA to evaluate four of these new studies. In June 2018, EFSA published its evaluation<sup>9</sup>, whereby it did not consider the four studies would warrant re-opening its 2016 scientific opinion. The EFSA expert panel recognised that the four studies evaluated did highlight some concerns, albeit with uncertainties. It recommended further research to decrease the level of uncertainties.

Eventually, in a most recent scientific advice<sup>10</sup> released on 15 April 2019 and taking into account the latest available evidence on the health effects of E 171<sup>11</sup>, the French food safety agency, ANSES pointed once more at persisting scientific uncertainties and insufficient data making it impossible to set an ADI for E 171. ANSES recommended to improve the physicochemical characterization of E 171 in order to allow for the full assessment of the risks associated with the consumption of this additive. It also recommended to conduct additional reproductive toxicity and, possibly, *in vivo* genotoxicity studies to better characterise the potential hazards associated with E 171. Finally, ANSES reiterated its previous conclusions<sup>12</sup> pertaining to products containing nanomaterials in general, namely that worker, consumer and environmental exposure to such products should be minimised, notably by promoting safer alternatives free from nanomaterials, so long as uncertainties remain over their safety.

Considering these uncertainties and data gaps, which prevent the complete risk assessment of E 171 and do not allow lifting remaining concerns over its potential toxicity for consumers, the precautionary principle should apply, and E 171 should be removed from the EU list of permitted food additives.

It is remarkable that the French government partly justified<sup>13</sup> its decision to suspend the use of E 171 over manufacturers' failure to provide the necessary data to conduct the risk assessment. The 'no data, no market' principle, which prevails in the chemicals sector under the REACH legislation, must equally apply to regulated substances in the food area, such as food additives, in order to prove their safety. In December 2018, EFSA recognised<sup>14</sup> that the additional data submitted by industry is still not satisfactory.

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<sup>8</sup> Bettini *et al.* Food-grade TiO<sub>2</sub> impairs intestinal and systemic immune homeostasis, initiates preneoplastic lesions and promotes aberrant crypt development in the rat colon, *Scientific Reports*, 7:40373.

<sup>9</sup> EFSA [evaluation](#) of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171)

<sup>10</sup> ANSES [scientific opinion](#) on the health risks associated with E 171 ingestion published on 15 April 2019.

<sup>11</sup> The most recent evidence on the health effects of E 171 includes notably the following studies:

- Gender difference in hepatic toxicity of titanium dioxide nanoparticles after sub-chronic oral exposure in Sprague-Dawley rats, Chen Z *et al.*, *Journal of Applied Toxicology*, 2019: the study examined female and male rats administrated with TiO<sub>2</sub> nanoparticles orally at doses of 0, 2, 10 and 50 mg/kg body weight per day for 90 days. It found significant hepatic toxicity that could be induced by sub-chronic oral exposure to TiO<sub>2</sub> nanoparticles.
- Exposure to Titanium Dioxide Nanoparticles During Pregnancy Changed Maternal Gut Microbiota and Increased Blood Glucose of Rat, Mao Z *et al.*, *Nanoscale Research Letters*, 14:26, 2019: the study pointed out that TiO<sub>2</sub> nanoparticles induced the alteration of gut microbiota during pregnancy and increased the fasting blood glucose of pregnant rats, which might increase the potential risk of gestational diabetes of pregnant women.
- The food additive E171 and titanium dioxide nanoparticles indirectly alter the homeostasis of human intestinal epithelial cells *in vitro*, Dorier M *et al.*, *Environ. Sci.: Nano*, Advance Article, 2019: the study found that TiO<sub>2</sub> moderately but significantly dysregulates several features that contribute to the protective function of the intestine.

<sup>12</sup> <https://www.anses.fr/en/content/assessment-risks-associated-nanomaterials>

<sup>13</sup> [Press release](#) issued by the French Ministry of Ecological Transition.

<sup>14</sup> [Minutes](#) of the 18 December 2018 meeting of the EFSA Scientific Panel on Food Additives and Flavourings' Working Group on specifications of food additives

- Technological need: There is no convincing technological need for the use of E 171. As a result of political and public pressure, many food manufacturers and retailers operating on the French market have already removed E 171 from their products or are in the process of phasing it out<sup>15</sup>. Over at least 150 foodstuffs which used to contain E 171 have been reformulated to become 'E 171 free' in a very short period of time<sup>16</sup>. Smaller producers, who might arguably face greater technological hurdles than bigger operators, have been offered support from their professional organisations to get rid of E 171 in their products<sup>17</sup>. And the move is even spreading beyond Europe<sup>18</sup>, with some multinational companies having committed to remove E 171 from their food portfolio.
- Benefits and advantages for the consumer: E 171 is only used for aesthetic purposes. It has no nutritional value, nor does it fulfil any beneficial technological function in food (e.g. extending shelf life).

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<sup>15</sup> May 2018 [update](#) by Agir pour l'Environnement.

<sup>16</sup> Online [inventory](#) (non-exhaustive) by Agir Pour l'Environnement.

<sup>17</sup> April 2018 [press release](#) by the French Ministry of Economy and Finance.

<sup>18</sup> [Press release](#) by the US consumer group, the Center for Food Safety reporting on Mars announcement to phase out artificial food colours, including E 171, from food products.