**Follow up to the European Parliament non-legislative resolution the draft Commission regulation amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards
specifications for titanium dioxide (E 171)**

**(2020/2795 (RSP))**

1. **Resolution tabled pursuant to Rule 112(2) and (3) of the European Parliament's Rules of Procedure**
2. **Reference numbers:** 2020/2795 (RSP) / B9-0308/2020 / P9\_TA-PROV(2020)0255
3. **Date of adoption of the resolution:** 8 October 2020
4. **Competent Parliamentary Committee:** Committee on Environment, Public Health and Food Safety (ENVI)
5. **Brief analysis/ assessment of the resolution and requests made in it:**

The draft Commission regulation aims at updating the specifications of the permitted food additive titanium dioxide (E 171) laid down in Regulation (EU) No 231/2012, in line with the recommendations from the European Food Safety Authority (EFSA), so that they better describe the physicochemical and purity characteristics of the substance authorised as a food additive. The concerns expressed in the resolution are not directly linked to the draft amended specifications, but to the existing authorisation of titanium dioxide as a food additive in Regulation (EC) No 1333/2008.

The resolution refers to data gaps and to uncertainties concerning the safety of the food additive titanium dioxide (E 171) (**recitals E** to **J**), a decree adopted by the French Government suspending the placing on the market of foodstuffs containing the food additive titanium dioxide (E 171) as of 1 January 2020 due to safety concerns (**recital K**), the lack of a proposal from the Commission removing the authorisation for the food additive titanium dioxide (E 171) (**recitals L** and **M**), the use of the precautionary principle (**recitals N** to **Q**), the technological need and benefit to consumers of the food colour E 171 (**recitals R** to **T**) and the labelling of nanomaterials in foodstuffs (**recital U**).

The resolution states that the draft Commission regulation is not compatible with the aim and content of Regulation (EC) No 1333/2008 on food additives and Regulation (EC) No 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings (**paragraph 2**). It also states that continuing to allow titanium dioxide (E 171) to be placed and sold on the market as a food additive runs counter to the provisions of Article 6 of Regulation (EC) No 1333/2008 and may have adverse effects on the health of European consumers (**paragraph 3**).

The resolution calls on the Commission to withdraw the draft Commission regulation and to apply the precautionary principle and to remove titanium dioxide (E 171) from the Union list of permitted food additives (**paragraphs 4** and **5**)

1. **Response to the requests and overview of the action taken, or intended to be taken, by the Commission:**

Regarding **paragraph 2**, the Commission considers that the draft regulation is fully compatible with the aim and content of Regulation (EC) No 1333/2008 on food additives and Regulation (EC) No 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings. It is based on recommendations from EFSA in the 2016 re-evaluation of the safety of E 171 as well as EFSA’s 2019 scientific opinion specifically dealing with the specifications for E 171. The draft amended specifications for E 171 better characterise the substance used as food additive by introducing mandatory particle size parameters (proportion of particles in the nanoscale) and clarifying that E 171 does not have surface treatments or coatings. In addition, the maximum levels for impurities of antimony, lead, mercury and cadmium are reduced to ensure that E 171 will not be a significant source of exposure to those hazardous elements through food. Moreover, the draft amended specifications will allow a better identification of the criteria that should be used for any new toxicological studies on the safety of E 171, especially as regards the quantity of nanoparticles

Concerning **paragraph 3**, the Commission considers that titanium dioxide (E 171) meets the safety requirement included in the general conditions for inclusion of food additives in the Union lists of authorised food additives, laid down in Article 6 of Regulation (EC) No 1333/2008. EFSA re-evaluated the safety of E 171 in 2016 and concluded that the available toxicological as well as use/use-level data in food do not indicate health concerns for consumers. Nevertheless, to address some remaining uncertainties, EFSA issued recommendations on additional reproductive toxicity testing and on a better characterisation of the substance in the specifications for E 171, in particular as regards its particle size distribution. In order to address these recommendations, the Commission issued a call for data in 2017, and business operators provided the requested data*.*

Since then, EFSA issued three additional opinions on E 171: 1) 2018 opinion on four new studies on the safety on E 171; 2) 2019 opinion assessing an opinion from the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) on E 171 which was used by France as the basis for its national measures; 3) another 2019 opinion on the specifications for E 171. In all cases, EFSA re-confirmed its previous conclusions about the safety of E 171 (i.e. no evidence of health concern for consumers), and indicated that the uncertainties identified (which are addressed in the requested and recently concluded reproductive toxicity study) remain the same. (**paragraph 5**).

The Commission considers that titanium dioxide (E 171) also meets the non-safety related general conditions for authorisation of food additives laid down in Regulation (EC) No 1333/2008 (namely, that there is a reasonable technological need, that it does not mislead the consumer and that it improves the organoleptic properties of food). In this respect, it should be noted that “colours” is one of the food additive functional classes listed by the co-legislators. Titanium dioxide (E 171) also meets the specific conditions for “colours” in Regulation (EC) No 1333/2008 (namely, restoring the original appearance of food, making food more visually appealing and giving colour to food otherwise colourless). Regulation (EC) No 1333/2008 does not require that food colours have nutritional value. In all these instances, the Commission scrupulously applies the legislation.

Concerning the French Order suspending the placing on the market of foodstuffs containing the food additive titanium dioxide (E 171) as of 1 January 2020, for one year (renewable), which was notified to the Commission on 26 April 2019, the Commission consulted the Member States on 13 May 2019. A majority of them highlighted the importance of keeping harmonised rules for food additives in the Union. They also indicated that EFSA should continue to be the Union reference for the scientific advice, also for the safety of titanium dioxide (E 171) as a food additive. There was a general lack of support from the Member States for the extension of the French measures to the whole Union. Several Member States asked for a swift follow-up to the 2019 EFSA opinion on the specifications for E 171 by amending the current specifications in accordance with EFSA’s recommendations (the object of the current draft Commission regulation). Most Member States were of the view that an EU decision on the French measures against E 171 should be taken on the basis of a new EFSA opinion which will assess the results of the requested and recently provided reproductive toxicity study.

In the meantime, business operators have submitted the results of this reproductive toxicity study, and the Commission has requested EFSA to carry out a reassessment of the safety of the food additive E 171. For this, EFSA will take into account the new toxicological data generated by business operators and all new information on the safety of E 171 that has become available since EFSA published its opinion in 2016. In addition, for this reassessment EFSA will also apply for the first time its 2018 guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA is expected to deliver its opinion in March 2021.

The Commission takes note of the Parliament’s position. As the current draft regulation cannot be adopted or re-tabled as it stands, the Commission will reflect further on the most appropriate way forward, taking into account that, according to the existing EFSA scientific opinions on E 171, there are no safety concerns for consumers that would justify its removal from the list of permitted food additives, and that the outcome of the reassessment of the safety of the food additive titanium dioxide (E 171), on which EFSA is currently working, will not be available before March 2021.