TDMA
TITANIUM DIOXIDE MANUFACTURERS ASSOCIATION
for a brighter future

[redacted]
Directorate-General for Health and Food Safety
European Commission
Rue Breydel 4
1040 Brussels

By email: [redacted]@ec.europa.eu

Brussels, 8 May 2019
Our reference: 1027b

Re: French measure suspending E171 (titanium dioxide) in foodstuffs

Dear [redacted],

I am contacting you on behalf of the Titanium Dioxide Manufacturers Association (TDMA), a sector group of Cefic, which represents the leading producers and suppliers of titanium dioxide (TiO_2) in Europe regarding the new French measure suspending titanium dioxide (E171) in foodstuffs.

We believe this unilateral decision of the French government is not scientifically justified and will result in distorting the European Single Market as well as undermining the EU risk assessment process led by the European Food Safety Agency (EFSA).

The use of additives in foodstuffs is subject to harmonised EU legislation and under Regulation (EC) No 1333/2008, the use of E171 is permitted in several food categories. The French decision to unilaterally suspend the placing on the market of food products containing E171 would not only **set an important precedent undermining the fundamentals of the Internal Market and EU harmonised legislation**, but it would also severely undermine the role of EFSA's risk assessment. Considering the importance of maintaining the Single Market, we believe that any potential modification of the authorisation of the use of TiO_2 in food in the EU should be based on an analysis of available data carried out by EFSA.

We would like to stress that **there is no sufficient or robust scientific evidence justifying the suspension of E171**. Indeed, in more than 50 years of use as a colourant, no verifiable link has ever been shown between the general intake of TiO_2 and ill health in humans. E171 has gone through rigorous European testing and classification, which proved that TiO_2 has not been found to persist or accumulate in the human body or the environment. Notably, the European Food Safety Authority (EFSA) confirmed in 2016

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that data on E171 showed no health concerns for consumers and reaffirmed its conclusion last year based on a review of additional data.

We recognise that recent studies (including *Bettini and al.*, referred to in the ANSES Report 2019-SA-0036 dated 12 April 2019) have raised concerns over the safety of E171. The industry has considered this as part of its **comprehensive science programme aimed at addressing possible concerns over TiO_2** more broadly. As part of this program, the Michigan State University (MSU) and the University of Nebraska Medical Centre looked at the effect of the administration of E171 in male rats to address concerns raised by the Bettini study. Initial results have been shared with the European Commission and the French environment agency (ANSES) and the study has now been completed with no adverse effects shown. You will find attached the most recent summary of this work.

About the concerns over the determination of an Acceptable Daily Intake (ADI), TDMA has commissioned, in consultation with the European Commission, EFSA and ANSES, an extended one generation reproduction toxicity study (EOGRTS). The results were originally planned for mid-2019, but to assuage some concerns expressed by ANSES, the industry accepted to extend the original scope of the study to address potential adverse impacts of E171 on the colon, which slightly delayed the work.

Furthermore, TDMA completed a physicochemical testing program of the different types of E 171 on the market using external third-party laboratories. This ensured that the sample selected was well characterised and selected based on the smallest particle size. This was to address long standing concerns raised by ANSES about different grades of TiO_2 on the market and the relevance of studies. This analysis and data was shared with EFSA and ANSES. The Commission plans to revise and narrow the definition of E171, possibly in 2019, based on this work which could help to address remaining concerns about the safety of E171.

Therefore, it seems misleading to base the current French measure on the lack of data provided by industry while the timing was especially driven by the commitment of the industry to address concerns raised by the Authorities. TDMA is currently carrying out the work to the highest possible standards with a firm completion date of July 2020.

We believe it is critical to act quickly to defend the current EU regulatory process and Single Market and we ask that you firmly object to the French decision unilaterally suspending the placing on the market of foods containing E171. As a minimum, we believe the entry into force of the French measure should be delayed until 1 January 2021 to consider the EOGRT study results.

We remain available should you have any further questions on this issue and hope you will consider the facts and data presented above.

Yours sincerely

CC: , DG SANTE, by email - @ec.europa.eu
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Annex I - Evaluation of immunologic and Intestinal Effects in Rats Administered E171