

Director General

EUROPEAN COMMISSION
DGENVIRONMENT
DG Daniel Calleja Crespo
Mr. Kestutis Sadauskas
Avenue Beaulieu 5
1160 Auderghem

3 March 2019

Dear Director General Calleja Crespo, Dear Daniel,

Dear Director Sadauskas, Dear Kestutis,

I would like to raise your urgent attention to the fact that on the **classification of titanium dioxide**, I believe we are heading in the wrong direction. This is the reason I have approached DGENV and we have the meeting with Mr Sadauskas on Tuesday the 5th of March.

As we have little time left, I already want to raise these points in a letter to you ahead of the meeting. The discussions around titanium dioxide have much wider implications than for the substance alone, which is why as Cefic DG, I think it is of importance to share this with you.

In a file that has been in discussion for quite some time, **the REACH Committee is still very much divided**. The REACH Committee will meet on 7 March to discuss and possibly vote on the 14th amendment (ATP). So far, Member States have not been able to agree on the Commission's proposal to classify titanium dioxide.

The issue has become **politically very sensitive**. The reaction of several Member States against the ATP listing for titanium dioxide validates our concerns that this is a politically sensitive rather than just a technical file. Today, there appears to be no qualified majority either for or against the ATP listing if titanium dioxide is included. If titanium dioxide is removed, the ATP update will be adopted. The political sensitivity increases even more just ahead of the upcoming elections.

Out of the 489 submissions to the Better Regulation Public consultation on the 14th adaptation to technical progress (ATP) of the Classification and Labelling (CLP) Regulation launched on 11 January 2019, about **438 raised concerns** about the proposed classification for titanium dioxide. **This is unique**. Whilst existing points were raised, new and unexpected issues emerged in the stakeholder submissions.

A key concern is that the still changing Commission proposals, the impact of the classification on waste streams still has not been resolved. We welcomed the Commission's statement to Member States that they will address the waste issue. We have understood an effort has been made to avoid building and construction waste streams to become hazardous waste. There is however a second order impact of classification, which were raised from the very start. The problem has not been solved.

Unlike for other substances, we have been told that titanium dioxide is often used at levels above 1% of weight of the final article. Examples include:

- Almost all paints and coatings (95% of paints use TiO₂)
- Plastics:
 - Plastics (engineering and decorative): 1-10%;
 - uPVC windows: 2-4%;
 - PVC plastisol: 5%; and
 - Packaging films and containers: 1-20%.
- Paper
 - TiO₂ levels can typically be in the 20-40% range of the décor paper. In wallpapers, TiO₂ may be found in concentrations in the range of 1-10%.
- Almost all Inks
- Concrete, mortars, grout, plaster: 0.1-10%; and Sealants and adhesives: 1-15%.
- Colour pastes for silicone rubbers: 30-55%; Silicone: 1-5%; General rubber goods (GRG): 0.5-20% (depending on the application);
- Porcelain enamels: 5-25%; Ceramic pigments: 5-60%
- Ceramic glass colours: 4-20%; and Special glass: 1-30%

We hope we are wrong, but as we understand the European waste legislation, these concentrations mean that waste from **many high-volume waste streams would be deemed hazardous, unless exempted, due to the links between waste classification and the CLP**. This will apply even when titanium dioxide is fully bound and not inhalable **as route of exposure (form and size) is not accounted for in waste legislation**. The Commission's [communication](#) on the issues in chemical, products and waste interface highlights the challenges to decide which wastes and chemicals are hazardous.

Additional measures are needed to solve this. This matter can be addressed by pro-actively updating the Commission Decision 2000/532/EC, establishing a list of hazardous waste, and deeming waste from such sources as non-hazardous. This update should then however be concurrent to the classification process. If all of the articles above will become hazardous at their end of life, much of the 'circular economy' will be stopped before it has the chance to flourish. Several submissions to the public consultation highlighted the extent of these impacts.

And an Impact Assessment is warranted but not available. The Commission's Better Regulation Guidelines provide an administrative system where the Commission can consider the full impact of their proposals before adopting it. For secondary legislation, often focused on technical matters, there is no need for an automatic impact assessment.

Yet, the Better Regulation Guidelines, Toolbox 40, makes clear that "Impact assessments should be prepared for delegated and implementing acts when the expected economic, environmental or social impacts of EU action are likely to be significant and the Commission has a margin of discretion regarding the content of the act. The principle of proportionate analysis applies and the appropriate level and focus of the impact assessment is linked to the type of policy initiative" (page 299).

The public consultation has revealed expected and many more unexpected significant impacts from the titanium dioxide ATP listing. Even at this late stage, an impact assessment, even an expedited one, would answer many of the questions raised by many Member States and others. It would lead to a better-informed decision.

An impact assessment is possible. The Commission Services have already exercised a considerable margin of discretion by not simply tabling the RAC's opinion directly into the ATP, so initiating an impact assessment is not unwarranted. Undertaking an Impact Assessment would answer the many questions from Member States and others. The Commission's own guidelines anticipated that even on the face of its technical files may raise more significant issues and deserve broader consideration. And, if after all, the impact assessment confirms the Commission Services' current view on the proposed path forward, it will ensure an adoption with no objections.

We ask to remove titanium dioxide from the ATP to allow this. We understand that this is a big step, especially so late in the process. Some member states will not agree, but the chances of the ATP going through without titanium dioxide are higher than with titanium dioxide. There are ample reasons to answer the questions from member states and stakeholders before proceeding.

Especially as there are new developments to take note of, on OEL and on Substance Evaluation.

OEL Prioritization. DG Employment has informed stakeholders that titanium dioxide is a priority substance for the 6th list for indicative Occupational Exposure Limit Values under the Chemical Agents Directive (CAD; 98/24/EC) (attached). The submissions to the public consultation across various sectors agreed that the inhalation concerns described by the RAC for titanium dioxide are only relevant in the workplace. This mirrors the outcome of the European Commission titanium dioxide technical meeting (23 April 2018) which concluded that the hazard described for titanium dioxide is limited to the workplace.

Many of the submissions stress that occupational health and safety measures could be used to effectively and proportionately address these concerns. This echoes the views of the German government. Another advantage of using the OEL path to deal with titanium dioxide, is that it would allow the RAC to re-look at the latest science and information and re-address the issue. Doing so in an expedited manner would not withdraw the matter, but allow an opportunity for the RAC to re-look at what they themselves note is a special case. The ATP could, if needed, then be updated in light of the RAC's review.

Substance Evaluation. France will conclude their REACH substance evaluation (CoRAP) for titanium dioxide in March. It is likely that France will propose further regulatory action. Addressing the classification within a broader context would be an option.

And finally, it is worthwhile to look at the science again. The public consultation feedback raised important and new scientific evidence (Feedback references: [F25855](#) , [F25162](#), [F18135](#) and [F22795](#)). The proposed classification is based on a single hazard study (Heinrich et al.,1995) which did not conform to OECD or CLP scientific guidelines, and which was excluded by ANSES in the original CLH dossier. As the Heinrich study was not a part of the original CLH dossier, stakeholders logically provided no feedback on this study during the public consultation on the original proposal. The analysis by leading scientists showing the deficiencies of this study was not considered by the ECHA RAC.




Since the end of the consultation, a new study has been published which reviews the state of the art regarding inhalation toxicology for poorly soluble particles. Given this new evidence, it would be relevant for the Commission to seek advice of ECHA before proceeding.

In summary, there is many sound public policy reasons why the ATP update can best go ahead without titanium dioxide at this stage. We ask you to assess our arguments above and look forward to discuss these on Tuesday.

Yours sincerely,



Marco Mensink
Director General Cefic

cc: , DGENV
Carlo Pettinelli, DGGROW
, DGGROW
, SECGEN