

To:
Ms Céline Gauer
Deputy Secretary-General

Secretariat-General
European Commission
Brussels

By email:
celine.gauer@ec.europa.eu

Brussels, 10 September 2019

Re: Impact Assessment, 14th adaptation to technical progress (ATP) of the Classification and Labelling (CLP) Regulation – titanium dioxide (TiO₂)

Dear Ms Gauer,

We understand that the proposal to classify Titanium Dioxide (TiO₂) as a suspected carcinogen (cat. 2) by inhalation as a part of the 14th ATP to the CLP Regulation will be discussed as a delegated act on 18 September in the CARACAL Committee.

489 interested parties contributed to the [public consultation](#) on the 14th ATP and third countries made [submissions](#) via the WTO technical barriers to trade notification process. These parties have all raised similar concerns regarding the proposed delegated act, and the common questions relate to:

1. **The political sensitivity of the classification, and;**
2. **The potential unwarranted second order impacts, especially on circular economy.**

To resolve the questions raised, many of the interested parties have suggested to undertake an impact assessment before deciding on the proposed classification of TiO₂ to bring full clarity.

The Commission's position to date has been to suggest that the translation of the proposed classification by the European Chemical Agency's Risk Assessment Committee (RAC) should be automatically transposed into the CLP Regulation.

However, this position is not reflected in practice and in the text of the CLP Regulation. Firstly, the Commission Services have from time to time exercised their inherent discretion in taking forward individual classifications, confirming that there is no automaticity in taking forward the RAC's opinion and the text put forward in the ATP package (e.g. [2015](#) and [2016](#) ATPs). Secondly, the Commission has an affirmative duty under article 37(5) of the CLP Regulation to verify if CLP classification is the right action and to consider relevant classification and labelling elements, such as concentration limits etc.

In this regard, the Better Regulation Guidelines are clear that technical and secondary legislation, like delegated acts, can benefit from an impact assessment: "The lead DG should (in consultation with the Secretariat-General) consider whether the Commission's initiative would benefit from further analysis and a complementary IA due to its complexity, or the significance of the expected impacts or where the Commission is likely to deviate from the advice of the relevant agency or indeed where the Agency's work does not meet the Commission's usual standards" ([Better Regulation Toolbox, page 51](#)).

In this case, the impact assessment would be a useful instrument to determine the way forward:

- 1) The division in the views of the Member States shows, this issue is politically sensitive. Several Member States have raised questions about the impact of classification;
- 2) The second order impacts of the proposed classification are at best unanswered and unclear to many. The recent fitness check of the most relevant chemicals legislation (excluding REACH) highlighted the negative consequences of unintended second order impacts;
- 3) Due to the circular economy impacts, DG ENV is working on an update to EU waste guidance. The impact assessment can clarify whether it is adequate to avoid the unintended impacts on the circular economy highlighted by the affected sectors and the waste management industry.

The Commission has previously undertaken impact assessments for delegated acts in relation to issues around Endocrine Disruptors.

As shown by the many hundreds of comments on the 14th ATP, the public consultation is an important instrument to gather feedback from stakeholders. We now understand that the Commission intends to remove this important step from the CLP process, and it is claimed that the consultation on the 14th ATP was due to clerical error.

We are concerned about this approach, which would go against the letter and the spirit of Better Regulation. The Commission, the Member States, and MEPs all benefit from letting the people tell them what they think of the laws being passed in their name. To remove the public consultation for the ATP would deprive many of the opportunity give their feedback on the final proposal.

In the light of this, we ask that the Commission undertakes an impact assessment on the proposed classification for TiO₂ before proceeding with the delegated act. Even an expedited impact assessment would bring forward important information before making a decision on this file.

Sincerely,

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Association of Chemical Industry of the Czech Republic	
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Association of Paint Manufacturers of the Czech Republic	
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BureauLeiding	
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Carlos Grollo S.A.	
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CEPI – Confederation of European Paper Industries	
CET Comité Européen de la Tréfilerie	
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Disbon GmbH	
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Dothée SA	
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Druckfarben Hellas S.A.	 
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Dutch Association of the Paint and Printing ink industry: VVVF	
DVSI e.V.	
ECKART GmbH	
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EEIG OF INORGANIC PIGMENTS	
EFCC (European Federation for Construction Chemicals)	

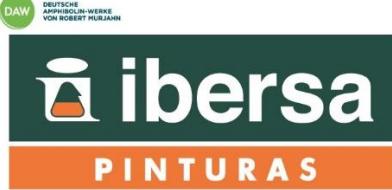
einzA Lackfabrik GmbH	
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ELASTÓMEROS RIOJANOS S.A.U.	
Epple Druckfarben AG	
ER-LAC G.D. KOUTLIS S.A.	
ESTAL, European Association for Surface Treatment on Aluminium	
Estonian Chemical Industry Association (ECIA)	
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European Wood-based Panels Federation (EPF)	
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Fachverband Werkzeugindustrie e. V	
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<p>INDUSTRIAS QUÍMICAS SATECMA</p>	
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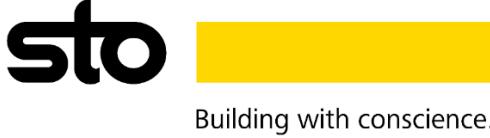
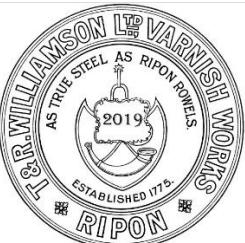
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WSM Wirtschaftsverband Stahl- und Metallverarbeitung e.V.	 <p>Wirtschaftsverband Stahl- und Metallverarbeitung e.V. Düsseldorf • Hagen</p>
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Zentralverband Oberflächentechnik e.V	

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