



EUROPEAN COMMISSION  
SECRETARIAT-GENERAL

Deputy Secretary-General - Policy Coordination

Brussels,  
SG.DSG2.

Mr [REDACTED]  
European Chemical Industry  
Council - Cefic aisbl  
[REDACTED]@cefic.be

Dear [REDACTED]

Thank you for your letter of 21 June 2019 about your organisations' procedural concerns regarding the decision-making process for the classification of titanium dioxide.

I would like to underline that the proposed measure on the classification of titanium dioxide has followed the normal procedures for a harmonised classification proposal.

Our approach to better regulation for the classification measures is based on the scientific advice provided by the Risk Assessment Committee in the European Chemicals Agency. The Risk Assessment Committee's opinion is based on an assessment of all available scientific information and includes an extensive consultation process, where stakeholders can provide input and raise concerns, which are taken into account as appropriate.

For the harmonised classification you refer to, the European Chemicals Agency received 514 comments in the consultation on titanium dioxide. For the Risk Assessment Committee's final opinion, these comments have been considered and replied to as part of the opinion (see Annex 2 to the opinion).

In addition to the consultation carried out by the European Chemicals Agency, the Commission also organised a consultation through the public feedback mechanism on the draft act. This act introduces harmonised classification to Annex VI of the CLP (classification, labelling and packaging) Regulation for several substances in addition to titanium dioxide (the 14<sup>th</sup> adaptation to technical progress of the CLP Regulation). The consultation resulted in 489 comments, which were taken into consideration by the Commission for possible adaptations of the draft legal text. The content of the comments on titanium dioxide were mainly reiterations of previously made comments by stakeholders.

Moreover, additional activities have unfolded to engage with and reply to concerns raised by the industry throughout the process, such as in the CARACAL expert group, in additional meetings between stakeholders and different Commission services (e.g. ENV, GROW or the Secretariat-General) or via the exchange of several letters. These efforts

were made to ensure an end-result, which achieves a high level of protection that can also be delivered on the ground in a circular economy. As a follow-up to the concerns raised, DG ENV is currently working on amending the guidance on waste classification to mitigate any possible unintended consequences on waste legislation.

In the future, all measures regarding harmonised classification will be adopted through the delegated act procedure, which is a change from the regulatory procedure with scrutiny used until recently. The act will therefore be provided with an explanatory memorandum, which will provide further transparency and explanations to the process.

Yours sincerely,



Celine DAUER

Contact:  tel. 

To:  
Ms Ilze Juhansone  
Deputy Secretary-General

Ms Céline Gauer  
Deputy Secretary-General

Secretariat-General  
European Commission  
Brussels

By email:  
[redacted]@ec.europa.eu  
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Brussels, 21 June 2019

Re: Better Regulation, 14<sup>th</sup> adaptation to technical progress (ATP) of the Classification and Labelling (CLP) Regulation – titanium dioxide (TiO<sub>2</sub>)

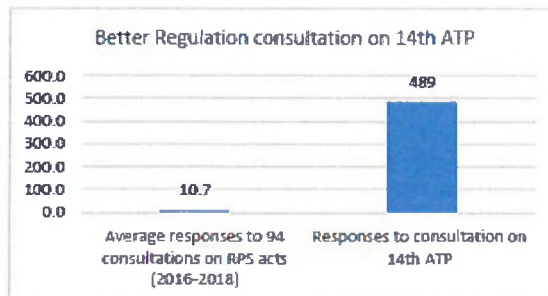
Dear Ms Juhansone and Ms Gauer,

The Better Regulation agenda is a commitment from the Commission to make EU policymaking more inclusive and efficient, by relying on solid evidence, understanding the impacts of EU decisions and listening more to the people affected by EU decisions. We are deeply concerned that the administration of the 14<sup>th</sup> adaption to technical progress (ATP) of the EU Classification and Labelling (CLP) Regulation contradicts these principles.

The Commission is not considering the answers to the public consultation on the 14<sup>th</sup> ATP despite a feedback level 46 times higher than average

In line with the Better Regulation guidelines (Better Regulation [toolbox 40](#), page 330), the 14<sup>th</sup> ATP to the CLP Regulation was opened to a four-week public [consultation](#). This consultation received 489 comments of which at least 430 related to the proposed classification of TiO<sub>2</sub>.

The overall amount of feedback for TiO<sub>2</sub> alone is 40 times higher than the average response rate observed in 2016-2018 on 94 acts under the Regulatory Procedure with Scrutiny ([SWD\(2019\) 156 final](#)). The high amount and the substance of the responses confirm that many believe there will be significant impacts.



We understand that the Commission is not obliged to provide individual feedback to submissions to the consultation (Better Regulation [toolbox 56](#), page 442-443). However, no explanation on how this feedback was taken into account in the proposal is included in the summary record of the following REACH Committee meetings at which a discussion and vote on the 14<sup>th</sup> ATP were scheduled in [February](#), [March](#) or [April](#). This is in clear contradiction with the requirements of the Better Regulation guidelines (Better Regulation [toolbox 56](#), page 443). So, to the best of our knowledge, the lead DGs have not undertaken an analysis of the feedback received nor presented an explanation to the Member State REACH Committee of how it has considered the feedback.

#### The Commission has a duty to undertake an impact assessment

The Better Regulation guidelines require that an impact assessment be carried out for secondary legislation when the expected economic, environmental or social impacts of EU action are likely to be significant and when the Commission has a margin of discretion regarding the content of the act (Better Regulation [toolbox 40](#), page 299). Both criteria are met in the case of the 14<sup>th</sup> ATP:

- The high response rate and the evidence provided in the public consultation showed that the expected impacts are significant. Although many of the submissions raise existing points, many new and unexpected issues emerged in the stakeholder submissions (see [annex](#)).
- In exercising discretion under Article 37(5) of the CLP Regulation, the Commission has the duty to fully assess all the relevant scientific and legal aspects of the proposed classification.

An impact assessment is not only required by the Better Regulation guidelines. It is a duty for the Commission to undertake an impact assessment under the 2016 [Inter-institutional Agreement](#) on better law-making for implementing measures which are expected to have significant impacts.

#### The 14<sup>th</sup> ATP can continue without TiO<sub>2</sub> to assess the impacts

First Vice-President Frans Timmermans, responsible for Better Regulation, recently [stated](#) that the EU needs to be closer to those who know whether EU rules may be needed and whether they may be working. He also asserted that stakeholders must be involved in an open and transparent process where their views and data have been considered seriously. The process around the public consultation on the 14<sup>th</sup> ATP falls short on these points.

Setting aside a consultation with a feedback level 46 times higher than average specifically concerning TiO<sub>2</sub> would alienate and frustrate the many stakeholders who invested time and efforts in gathering and providing inputs. More generally, in the context of the EU elections, it risks sending a strong negative signal about the EU's commitment to take the concerns of stakeholders seriously and to consider all available evidence in its policymaking.

To resolve this situation, we ask that the Commission observes the duty to undertake an impact assessment. The 14<sup>th</sup> ATP to the CLP can be allowed to proceed without TiO<sub>2</sub> while this step is completed. Afterwards, the decision on the regulatory way forward can be made on an informed basis considering all the available options, including those put forward in discussions by Member States.

Sincerely,



Titanium Dioxide Manufacturers Association



European Ceramic Industry Association



Committee of PET Manufacturers in Europe



European Aluminum



European Coil Coating Association



European Council of the Paint, Printing Ink and Artists' Colours Industry



European DIY Retail Association



European Federation for Construction Chemicals



European Mortar Industry Organisation



European Panel Federation



European Plastics Converters



Imaging and Printing Association



Toy Industries of Europe

Toy Industries of Europe

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**Key message on the way forward**

The overwhelming message of the commenters is to remove TiO<sub>2</sub> from the 14th ATP so it can proceed, while providing the necessary time to bring full clarity to the numerous questions and concerns. Commenters included not only industry, but also scientists, academics and individuals.

As the next step, many suggest that the Commission undertakes a Better Regulation impact assessment to answer the open questions and to consider the alternative regulatory options. Given the RAC's conclusion that the hazard profile described for TiO<sub>2</sub> is not intrinsic to TiO<sub>2</sub> but applies to all poorly soluble low toxicity substances (PSLTs), it is also widely recognised in the submissions that an effective and proportionate solution is needed for this broader issue, applying to >300 substances.

Numerous submissions express support for the German proposal to mandate a working group to find a harmonised regulatory approach to PSLTs before setting a precedent for an entire group of substances.

**Critical new information and substantive points raised in the consultation**

The Commission has said that it does not anticipate any significant impacts from the classification, but the comments from a broad spectrum of affected parties contest this assertion. On the contrary, they overwhelmingly point out the broad impacts that the current proposal would bring on their specific situations and businesses, which underlines the critical need for an impact assessment as required by Better Regulation guidelines for secondary legislation expected to have significant economic, environmental or social impacts<sup>1</sup>.

**1. Scientific evidence is available which has not been considered in the process**

Many submissions accentuate scientific questions and uncertainties in line with those described by the RAC. Submissions also emphasise that scientific evidence is available which has not yet been considered by the RAC (Feedback references: [E25855](#), [E25162](#), [E18135](#) and [E22795](#)):

- 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 for being of poor quality. As the Heinrich study was not relied on in the original TiO<sub>2</sub> CLH dossier, stakeholders logically provided no feedback on this study during the public consultation on the original proposal. The procedures of the RAC meant that analysis by world-renowned scientists showing the deficiencies of this study was not considered.
- The prevailing scientific consensus is that rat lung tumours induced by prolonged, excessive exposure to poorly soluble particles (PSPs) arise from chronic and persistent inflammatory changes (ECETOC 2013; Warheit et al, 2018). The rat species is unique in developing lung tumours following chronic overload particle exposures to PSP substances and is of questionable relevance to humans. (Warheit et al, 2018)
- A recent meta-analysis of epidemiology data for 24,000 workers in the TiO<sub>2</sub> industry, (Liu et al, 2018) demonstrates no association between worker life-time exposure to TiO<sub>2</sub> and lung cancer.

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<sup>1</sup> Better Regulation [Toolbox 40](#), page 299

## 2. Broad and damaging impacts on waste management and circular economy

The need for an impact assessment is widely recognized on the waste issue. Several respondents highlight that the classification would threaten the circular economy by disqualifying significant volumes of materials from recycling. The consultation brings forward new data regarding the magnitude of these impacts:

- A national waste management association highlights that about 50% of the total amount of plastics processed in Germany, equivalent to about 6.8 million tonnes, have TiO<sub>2</sub> levels of 1% or more. 2.6 million tonnes of plastic waste are generated annually, of which 1.6 million tonnes is packaging waste. Currently, 35% of plastic waste with ≥1% TiO<sub>2</sub> is being recycled (Feedback reference: [F25292](#)).
- EU associations for the plastics industry state that the current recycling of long life plastics applications excluding packaging (mainly building and construction but also automotive and E&E) is estimated at 600-700 kT; i.e., 30,000 to 35,000 truckloads. Those streams would have to be classified as hazardous waste (Feedback reference: [F25156](#)).
- An EU association in the plastics industry highlights that polyethylene terephthalate (PET) is the most recycled packaging resin in Europe and the market for white PET is 150,000 tons/annum. White PET packaging could become classified as hazardous threatening the EU recovery targets for the PET industry (Feedback reference: [F25178](#)).
- An EU association for the wood-based panel producers asserts that current procedures of reusing waste would be massively affected if paper or wood waste containing ≥1% TiO<sub>2</sub> were to be classified as hazardous (Feedback reference: [F23203](#)).
- A national association for the wood industry states that the classification of waste containing TiO<sub>2</sub> as hazardous would have a significant impact on waste wood. It can be assumed that waste wood assortments containing ≥1%TiO<sub>2</sub> can no longer be recycled (Feedback reference: [F25921](#)).

## 3. Serious questions regarding the legality of the proposed classification

The consultation provides legal analysis that the proposed classification for TiO<sub>2</sub> does not meet the legal requirements of the CLP and that the proposed measure breaches several general EU law principles:

- The submissions voice significant concerns that the classification breaches the EU principle of proportionality as alternative regulatory measures are available to address the hazard described by the RAC.
- Many submissions note that the CLP requires that the classification is based on an intrinsic property of the substance whereas the suspected hazard described for TiO<sub>2</sub> is a secondary dust effect, not intrinsic to the substance. An EU association for the paints industry describes that it has never been fully clarified in the regulatory discussions at the EU level whether the hazard described by the RAC is an intrinsic property of TiO<sub>2</sub> (Feedback reference: [F17923](#)).

The Titanium Dioxide Manufacturers Association makes a full legal review available, which concludes that the particle form of TiO<sub>2</sub> is not an intrinsic property of the substance (Feedback reference: [F18230](#)).



**4. Unintended negative impacts on a wide variety of perfectly safe, and in some cases critically important, consumer products**

The consultation gives new evidence on potential restrictions and negative repercussions on the efficiency of the CLP as a tool for hazard communication:

- An alliance of companies in the cosmetics industry stresses that although there are no concerns associated with the use of TiO<sub>2</sub> in cosmetics, the classification could result in a prohibition of the use of this ingredient in cosmetic and personal care products in Europe. They note that exemptions to the CMR cat. 2 ban are possible but can only be granted in very exceptional cases (Feedback reference: [F25294](#)).
- A stakeholder in the pharmaceuticals sector raises that even though the potential inhalation of TiO<sub>2</sub> concerns do not apply to pharmaceuticals, the classification could result in a negative risk assessment evaluation as the use of any excipient with a known potential toxicity should be avoided according to the European Medicines Agency (Feedback reference: [F2594](#)).
- An EU association representing the toy industry expresses concern that the current proposal would result in misleading labelling of perfectly safe toys negatively affecting consumer trust. The current draft means that a warning and safe-use instructions would be required also on a toy finger-paint that is not intended to be sprayed, and on solid-mixture toys where no significant amount of dust is formed (Feedback reference: [F23730](#)).
- An association in the retail sector highlights that the current proposal would mean that products containing bound titanium dioxide (not inhalable) should be labeled with the symbol GHS08 ("Health hazard"), the signal word "Warning" and the hazard statement H351 "Suspected of causing cancer". This would apply, inter alia, to:
  - wall and artist paints and varnishes
  - crayons, crayons, water-based paints and modeling compounds
  - adhesives, sealants and grouts
  - laundry care products
- The labeling of these products would lead to great uncertainty among consumers with very likely avoidance of these products (Feedback reference: [F25266](#)). Similarly, other submissions from the retail sector emphasize that risk communication is challenging already now (Feedback reference: [F18472](#)), and the proposed labeling will confuse consumers about the nature of the product they intend to buy (Feedback reference: [F18371](#)).

