From: [redacted] <[redacted]@cefic.be>
Sent: Monday, June 24, 2019 1:20 PM
To: JUHANSONE Ilze (SG) <[redacted]@ec.europa.eu>; GAUER Celine (SG) <[redacted]@ec.europa.eu>
Cc: [redacted] (SG) <[redacted]@ec.europa.eu>; [redacted] (SG) <[redacted]@ec.europa.eu>; [redacted] <[redacted]@cefic.be>
Subject: Joint letter - 14th ATP of the classification and labelling regulation - Titanium dioxide

Dear Ms. Juhansone and Ms. Gauer,

Please find attached a letter from a number of associations related to the above regulation, specifically to the inclusion of titanium dioxide, where a better regulation public consultation was **recently undertaken.**

We feel the apparent lack of consideration given to the feedback from this public consultation, which was 40 times higher than average, brings into question the process of better regulation. We are regularly requested and encouraged by the Commission to participate in consultations for a wide range of issues. It is difficult to encourage participation when one of the most widely responded consultations appears to be ignored. Please note, the Titanium Dioxide Manufacturers Association (TDMA) already sent a letter concerning this on 12 February 2019.

We would also like to request a meeting to discuss the workings of the better regulation process related to this issue.

We hope you understand our position and look forward to your response.

Best regards

[redacted]

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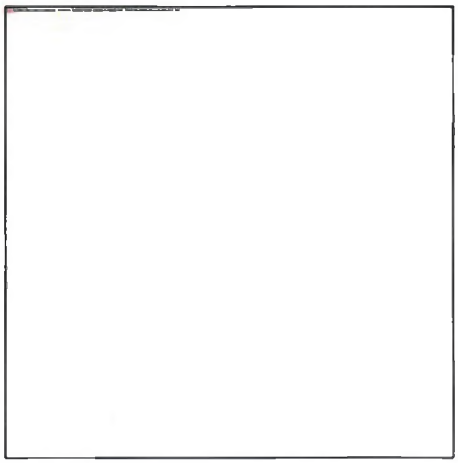

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Ref. Ares(2019)[redacted] - 28/08/2019

To:
Ms Ilze Juhansone
Deputy Secretary-General

Ms Céline Gauer
Deputy Secretary-General

Secretariat-General
European Commission
Brussels

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

Brussels, 21 June 2019

Re: Better Regulation, 14th adaptation to technical progress (ATP) of the Classification and Labelling (CLP) Regulation – titanium dioxide (TiO_2)

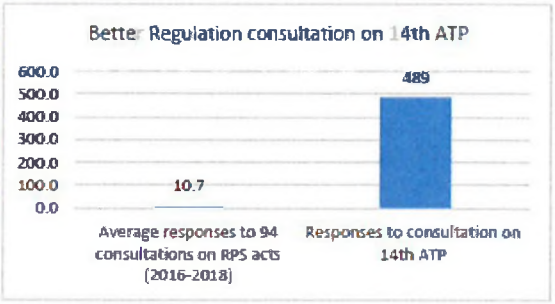
Dear Ms Juhansone and Ms Gauer,

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 14th 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 14th ATP despite a feedback level 46 times higher than average

In line with the Better Regulation guidelines (Better Regulation toolbox 40, page 330), the 14th 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_2.

The overall amount of feedback for TiO_2 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 14th 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 14th 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 14th ATP can continue without TiO_2 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 14th ATP falls short on these points.

Setting aside a consultation with a feedback level 46 times higher than average specifically concerning TiO_2 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 14th ATP to the CLP can be allowed to proceed without TiO_2 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

cc by email:

[redacted] ([redacted]@ec.europa.eu)

[redacted] ([redacted]@ec.europa.eu)

Annex: Summary of evidence provided in Better Regulation consultation

Key message on the way forward

The overwhelming message of the commenters is to remove TiO_2 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_2 is not intrinsic to TiO_2 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[1].

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: F25855 , F25162, F18135and 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 for being of poor quality. As the Heinrich study was not relied on in the original TiO_2 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_2 industry, (Liu et al, 2018) demonstrates no association between worker life-time exposure to TiO_2 and lung cancer.

[1] 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_2 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_2 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_2, were to be classified as hazardous (Feedback reference: F23203).
- A national association for the wood industry states that the classification of waste containing TiO_2 as hazardous would have a significant impact on waste wood. It can be assumed that waste wood assortments containing ≥1%TiO_2 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_2 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_2 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_2 (Feedback reference: F17923).

The Titanium Dioxide Manufacturers Association makes a full legal review available, which concludes that the particle form of TiO_2 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_2 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_2 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 labelling will confuse consumers about the nature of the product they intend to buy (Feedback reference: F18371).