Please see attached our letter regarding titanium dioxide (TiO$_2$) and the started Inter-Service Consultation on the 14th adaptation to technical progress (ATP) to the Annex VI of regulation (EC) No 1272/2008. We took the liberty to send this letter to several Commissioners.

We are convinced that the substance titanium dioxide is safe for consumers and has a societal function. The proposed classification broadens the scope of the regulation considerably and has unintended consequences such as no recyclability for millions of products. Alternatives for a way forward have not been fully explored. Please note that a considerable number of Member States remain with an objection to a classification according Annex VI. They point to non-existing exposure for consumers and extensive negative consequences for mixtures and articles that use TiO$_2$ (e.g. a ban of most colours from school-paint boxes).

We thank you for taking time to consider our letter and remain at your disposal for any further discussion with you on this measure.

Kind regards,
Inter-Service Consultation

on the 14th ATP list to the Annex VI of Regulation (EC) No 1272/2008

The European Commission services have started an Inter-Service Consultation with the aim to update Annex VI (Harmonised classification and labelling for certain hazardous substances) of Regulation (EC) No 1272/2008 for a total of 20 substances. We write to you concerning the substance titanium dioxide (TiO₂) which is included in this list. The industries represented by the signatory associations are users of TiO₂. We believe that the hazard that has been observed with this substance should not follow the way of an Annex VI entry and we have for that the following reasons:

**TiO₂ is safe for consumers and has a societal function**

TiO₂ is a chemically inert white powder that is widely used as pigment in products like paints, inks, plastics but also in many other industries such as paper, construction, glass, steel, pharmaceutical, cosmetics, leather, and textiles. It is used in any product that needs whitening. TiO₂ provides the highest opacity by far and has no equivalent technical replacement. The substance is an ingredient that is incorporated during manufacturing into these end-products. Consumers buy these end-products and have no access to the powder form of TiO₂.

**The proposed classification broadens the scope of the regulation considerably**

It is proposed to classify TiO₂ as Carcinogenic Cat. 2 'suspected of causing cancer by inhalation'. The observed toxicological effect result is not specific to the substance but to the overload mechanism that can be observed with any inert dust. A classification of TiO₂ will put dust effects into the scope of the regulation and thereby sets a precedent for roughly 300 substances with similar dust effects.

**There are existing safeguards for workers against dust**

Relevant dust levels of TiO₂ will only occur at the workplace where rules on occupational safety have to be followed. With no hazard for the consumer we consider a classification inappropriate. Warning the European citizen for inhalation of TiO₂ dust is ineffective or even misleading, because it is incorporated in the mixtures and lung overload is irrelevant. Exempting mixtures from classification would prevent at least this nuisance.

**Unintended consequences by a classification: no recyclability for millions of products**

Following the proposed classification, products at end of life or left-over that contain 1% or more of titanium dioxide would have to be considered as hazardous waste and could not be used for recycling. Other legislation would ban products that contain TiO₂. Under the toy safety directive most colours would be banned from school-paint boxes. To mitigate these impacts the European Commission services consider exemptions.
Alternatives for a way forward have not been fully explored

After expert meetings (CARACAL & REACH Committee) a considerable number of Member States remain with an objection to a classification according Annex VI. They point to non-existing exposure for consumers and extensive negative consequences for mixtures and articles that use TiO₂.

The Member States that object to a harmonised classification are in favour of a discussion on exposure levels for workers and consider occupational dust limits as the more appropriate instrument. Such alternative proposal has been tabled by Germany. It has no effect on downstream legislation and establishes safeguards where needed.

By using an Annex VI entry for TiO₂, the scope of the regulation would be broadened to roughly 300 substances which may be expected to show similar overload dust effects. If such inert dusts were subject to the rules for Occupational Health it would be a lot more effective and proportionate. Even with ‘mixture exemptions’ the downstream legislation has to be adapted with every next such substance.

Our request

We call on you to take note of the reasons mentioned here in evaluating the Annex VI entry of TiO₂ during this Inter-Service Consultation.

We remain at your disposal for any further discussion with you.

Yours sincerely,

Jan van der Meulen
Managing Director, European Council of the Paint, Printing Ink and Artists’ Colours Industry (CEPE)

Alexandre Dangis
Managing Director, European Plastics Converters (EuPC)

Dr. Roger Doome
Secretary General, Industrial Minerals Association – Europe (IMA-Europe)

Philip Bruce
Managing Director, Association of the European Adhesive & Sealant Industry (FEICA)

John Dixon
Director Regulatory Affairs, Flexible Packaging Europe (FPE)

Dr. Martin Kanert
Executive Manager, European Printing Ink Association (EuPIA)

Antonio Caballero González
General Secretary, European Mortar Industry Organization (EMO)

Mauro Scalia
Director Sustainable Businesses, European Apparel and Textile Confederation (EURATEX)

Dr. Alberto Arnava
Director General, European Federation for Construction Chemicals (EFCC)

Patrizia di Mauro
Secretary General, International Association of Painting Contractors (UNIEP)
Gustavo Gonzalez-Quijano  
Secretary General, The European Leather Association (COTANCE)

Beatrice Klose  
Secretary General, European Federation for Print & Digital Communication (INTERGRAF)

Bjoern-Markus Sude  
Director, I&P Europe Imaging & Printing Association (I&P Europe)

Susan Hancock  
Secretary General, European Lubricant Association (ATIEL)

Dr. Wilhelm Rauch  
Managing Director, Industrievereinigung Chemiefaser e.V. (IVC)
Subject: Closure of the alert procedure regarding the non-registered activities of the entity Titanium Dioxide Manufacturers Association (TDMA), a sector group of CEFIC (European Chemical Industry Council)

The Joint Transparency Register Secretariat (JTRS) refers to your alert TR-A-2018-72, which you submitted on behalf of Corporate Europe Observatory (CEO) on 10 July 2018 concerning the entities Titanium Dioxide Manufacturers Association (TDMA) and Venator.

As you were informed on 1 August 2018, in order to follow up to your alert, the Joint Transparency Register Secretariat has been in contact with CEFIC (TR ID: 64879142323-90), of which TDMA is a sector group, in order to receive additional clarifications with regard to the activities and status of this organisation.

It has emerged that as a sector group of CEFIC, TDMA does not have its own legal personality¹. All legal references on the TDMA website point to the legal personality of CEFIC, which is officially registered in Brussels, as stipulated in the Moniteur Belge, with the registration number 0412849915.² In fact, TDMA is one of up to 70 sector groups of CEFIC, none of which are currently registered in the Transparency Register directly.

¹ https://specialty-chemicals.co/tdma/
Therefore, while the JTRS cannot require that TDMA itself register in the Transparency Register, it has taken note of your concerns for more transparency regarding the activities of the sector groups of CEFIC. This is why, in its contacts with CEFIC, the JTRS has sought to identify possible areas of improvement in its declaration.

As a follow up to the alert, CEFIC has already taken the following measures to increase the transparency of its activities:

- CEFIC now includes the activities of CEFIC’s sector groups in its registration in the Transparency Register;
- CEFIC’s registration now provides a hyperlink to a full list of its sector groups (ca. 70) in its registration;
- CEFIC has given instructions to the staff of its sector groups to clearly identify themselves as such, when acting as representatives of CEFIC sector groups with the objective of directly or indirectly influencing the formulation or implementation of policy and the decision-making processes of the EU institutions.

In the context of this alert, the consultancy Fleishman-Hillard has also corrected its registration and no longer provides separate account statements for CEFIC and its sector groups.

Furthermore, the JTRS finds that while it may be neither warranted nor practical for CEFIC to oblige approximately 600 members to individually register in the Transparency Register, the JTRS has encouraged CEFIC to invite its members to register those activities that the latter perform in their own name and outside of CEFIC’s activities.

In this spirit the JTRS has also invited the entity Venator, which is a member of CEFIC, to register those activities in the Transparency Register falling outside the activities of the umbrella organisation and which are in the scope of the Interinstitutional Agreement on the Transparency Register.3

The JTRS finds the above implemented measures to be a sufficient and adequate response with regard to the case at hand, and fully in line with the guidelines for registrants. It has therefore decided to close the alert procedure.

Yours sincerely,

Maria Oliva Álvarez
Coordinator of the Joint Transparency Register
Secretariat

Subject: Meeting with CEPE on 18 July 2018 on the CLP classification of titanium dioxide

Participants: (CEPE); (EUPC); (EFCC) and (SG.D3)

The meeting was organised after several requests from CEPE with a view to inform about the potential CLP classification of titanium dioxide as a carcinogen.

Summary:

The CEPE participants explained the history of the file that had started off under unfortunate circumstances under REACH where France was in charge of a substance evaluation of titanium dioxide. In their work they wanted to focus on the smallest particles (nanomaterials), but this was rejected by the industry, leading to two cases at ECHA’s Board of Appeal. The ensuing consequence was that France then applied the results from two rat studies to conclude on the hazardousness of all forms of titanium dioxide. Even if the rat tests did not mimic any real-life exposures they were unanimously supported in the further process in RAC leading to the conclusion that titanium dioxide is a category II carcinogen.

If the Commission follows the normal logic of the CLP Regulation, this will have server consequences due to related regulatory triggers. All paints will be labelled and thereby diminish the purpose of labelling, but also lead to product bans (toys, cosmetics) and other disproportionate / unintended effects (building waste being hazardous, effects on eco-labelled products, public procurement of building materials).

CEPE supported a new proposal tabled last week by the UK and SI whereby titanium dioxide instead of being listed in Annex VI to CLP instead would have a new entrance in Annex II that will demand a softer kind of labelling on dusty mixtures. This could then be extended to other powders, which like titanium dioxide were not intrinsically hazardous, but formed a risk when inhaled, solely due to their small particle sizes.

Asked about CEPE’s views on the most recent informal proposal from ENV and GROW whereby most paint products would be excluded, they maintained that it was better than
the starting point, but that it would still leave open the question on waste and also many building materials (cement, mortar etc.).

SG welcomed the information and invited CEPE to continue their dialogue with ENV and GROW, who are lead services for the file.
On behalf of 15 European associations, the European Council of the Paint, Printing Ink and Artists' Colours Industry is pleased to submit a letter to you regarding the potential classification of Titanium Dioxide (TiO₂). Please find the industry statement enclosed to this email. We have sent similar letters to the European Commissioners Timmermans, Bieńkowska, and Vella.

We thank you for taking time to consider this important matter. We would welcome the opportunity to discuss our proposals at your convenience.
We would welcome an acknowledgment of receipt. Thank you in advance.

Kind regards,
Addressed to:
Mi Head of Unit D3 - Resource Efficiency, Secretariat General of the European Commission

Brussels, 31 May 2018
Industry Statement on the Harmonized Classification of Titanium Dioxide (TiO₂)

Dear Head of Unit D3

We would like to inform you of the intention by the Directorates-General GROW and Environment to classify Titanium Dioxide as ‘suspected of causing cancer through the inhalation route’. This will set a precedent with many significant impacts. As major downstream users of TiO₂, a potential labelling of most of our products or raw materials will entail strong consumer uncertainty and reservation, followed by commercial losses with impacts on growth and job security for our millions of employees, mostly at SME’s.

Following the RAC opinion of 14 September 2017, the relevant units consider tabling a proposal to update the Annex VI of Regulation (EC) No 1272/2008 as early as June 2018. According to the lead units, the legislative planning foresees a discussion at REACH Committee on the 13 June and a vote in September 2018.

Before tabling the proposal, we would welcome the consideration of our concerns and the acknowledgement of our proposals to first have an impact assessment on the classification or a risk management option analysis and the finalisation of the REACH substance evaluation on Titanium Dioxide. Please take into account the full-day CARACAL meeting on 23 April 2018, where several Member States including Germany questioned the classification of Titanium Dioxide and the continuation of the process as a whole.

According to the interinstitutional agreement of 13 April 2016 on Better Law-Making, the European Commission will carry out an impact assessment for secondary legislation which is expected to have significant economic, environmental or social impacts. A classification of Titanium Dioxide will have significant impacts on all three dimensions, which have not yet been considered at all. It is furthermore important to note that a classification will stand against the objective of (EC) No 1272/2008 and other EU initiatives like the EU Circular Economy. Therefore, we call for an impact assessment on the expected classification proposal or a risk management option analysis.

The proposed classification is merely based on a non-substance specific dust effect. If a dust effect were to be included into (EC) No 1272/2008, the scope of what is classified and labelled will be massively extended with an automatic domino effect on other legislations. Such precedent lays the foundation for a classification of potentially hundreds of other poorly soluble substances. A labelling of all Titanium Dioxide-containing products alone will lead to label fatigue, to the detriment of consumer protection and against the intention of the regulation to properly inform on hazard. Regulation (EC) No 1272/2008 could fail.

Following a classification, many materials containing more than one percent of Titanium
Dioxide would be considered as hazardous waste. This would become reality for a large variety of materials, including paints, inks, plastics, coated articles and construction products. In contrast to the EU Circular Economy, the aim of a high recyclability rate could not be achieved any more for those products. Since TiO$_2$ has the highest opacity among white pigments, the environmental footprint of paints containing TiO$_2$ substitutes will be much higher, as they require at least 3-4 extra layers of paint.

In addition, we would like to point to the importance of having a feedback period of 4 weeks on the draft measure. Currently, the relevant units are considering different derogations to fix the consequences of a classification. Until now, no enforceable entry or exemption has been proposed which would avoid inappropriate classification of mixtures. To our knowledge, the classification of dusts has never been discussed in Europe. With this dossier it is the right time to have a proper consideration before creating a precedent.

For all of these reasons, we call on you to apply the better regulation principles and to pursue a fundamental policy discussion that has started with the Member States – in particular to assess whether Regulation (EC) No 1272/2008 is the right regulatory instrument to address the concerns at stake, if any – before moving ahead with a classification of this individual substance on the grounds of a generic effect.

Finally, we would like to point to the ongoing REACH substance evaluation of Titanium Dioxide by France. We propose to first finish this parallel process, before considering any classification in order to ensure regulatory quality and alignment.

We thank you for taking time to consider this important matter. We would welcome the opportunity to discuss our proposals at your convenience.

Yours sincerely,

Jan van der Meulen
Managing Director, CEPE

Gustavo Gonzalez-Quijano
Secretary General, COTANCE

Dr. Alberto Arnavaas
Director General, EFCC

Antonio Caballero Gonzalez
General Secretary, EMO

Dr. Martin Kanert
Executive Manager, EuPIA

Manfred Meller
General Secretary, EWIMA

Bjoern-Markus Sude
Director, I&P Europe

Patrizia di Mauro
Secretary General, UNIEP

Alexandre Dangis
Managing Director, EuPC

Pierre Wiertz
General Manager, EDANA

Dr. Roger Doome
Secretary General, IMA-Europe

Mauro Scalia
Director Sustainable Businesses, EURATEX

Philip Bruce
Managing Director, FEICA

Beatrice Klose
Secretary General, INTERGRAF

Olaf Kral
Chair HSE Committee, ATIEL