



24 June 2019

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

There were no discussions in the REACH Committee in April regarding the proposal to classify TiO₂ as a suspected carcinogen (cat 2.) by inhalation and the June REACH Committee meeting was cancelled. This means that the next considerations are delayed to July or later pending the alignment of the CLP Regulation with the delegated acts procedure which is due to be [completed](#) shortly.

We want to bring attention to important new developments which are critical to the continued deliberations. We also want to bring attention to the new obligations for the Commission under the delegated acts procedure.

The burden of the unresolved circular economy issues will fall on the Member States

We welcome the Commission's acknowledgement that the CLP classification of TiO₂ would have unintended impacts on the circular economy and the efforts to address the issue by proposing an update to the guidance on the classification of waste (CA/23/2019). The guidance is a positive step, but it is not legally binding and thus we believe it is insufficient to avoid negative impacts on the circular economy. It is unclear when, and if, the update of the guidance will be completed, and no legislative changes are expected in the short to medium term to resolve the issue.

It thus appears that the waste and recycling issue created by the classification will not be tackled at EU level. It will be for the Member States to try to solve it, resulting in significant burdens for national authorities and fragmentation of waste management policies across Europe as confirmed by the Commission's recent [response](#) to a parliamentary question. This is unfortunate when alternative solutions presented by Member States are available which would effectively address the potential hazard while avoiding unwarranted downstream and waste issues altogether, such as the proposal for establishment of an EU harmonised occupational exposure limit by Germany.

Draft decision on substance evaluation of TiO₂ confirms that scientific questions remain unanswered

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) is currently undertaking a [REACH Substance Evaluation](#) of TiO₂, which is due to be completed shortly. In its draft decision, ANSES is requesting the TiO₂ industry to generate new data on the inhalation end-point. This underlines the open questions in the science, which were also articulated in the RAC's opinion, and later raised by the Commission in CARACAL doc. CA/90/2017.

The Titanium Dioxide Manufacturers Association's (TDMA) science programme, which has previously been presented to Authorities, is already at an advanced stage. The programme relates to the inhalation toxicity of 10 different TiO₂ types. The first stage is scheduled to be completed by December 2019 and the second part, a Comet Assay, is scheduled for completion in May 2020.

Given that these results are due to be delivered within a short timeframe, it would be reasonable to consider the substance evaluation before making a decision on the current classification proposal, in coherence with key principles of Better Regulation.

The delegated act procedure should respect the obligations under the Inter-Institutional Agreement

The delegated acts procedure is subject to the 2016 [Inter-Institutional Agreement](#) (IIA) on Better Law-Making between the Commission, the Council and the European Parliament. The importance of

respecting the principles of the agreement is underlined in the [amendment](#) to the CLP Regulation. Under point 13 of the IIA, the Commission must carry out an impact assessment for delegated acts, if these are expected to have significant economic, environmental or social impacts. The IIA also obliges the institutions to observe general principles of Union law, such as subsidiarity and proportionality, and legal certainty.

The [public consultation](#) on the 14th ATP, undertaken in line with Better Regulation guidelines, provided substantial evidence on the potential significant impacts of the classification. Numerous submissions also raised issues in relation to subsidiarity, proportionality and legal certainty. Yet, to our knowledge, the public consultation, for which the response rate was 46 times higher than average, remains completely unaddressed by the Commission, in contradiction of Better Regulation guidelines (Better Regulation [toolbox 56](#), page 443).

We call on the Member States to ensure that the Commission complies with the IIA and its Better Regulation guidelines to avoid a potential destabilisation of the institutional balance put in place by the IIA.

Sincerely,



Titanium Dioxide Manufacturers Association



Committee of PET Manufacturers in Europe



European Coil Coating Association



European DIY Retail Association



European Ceramic Industry Association



European Aluminum



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



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