6 July 2018

To Member State Competent Authorities of the REACH Committee:

Open letter: Classification of Titanium Dioxide (TiO_2)

We are writing to you regarding the discussion process in the REACH Committee on the classification of titanium dioxide (TiO_2) as carcinogen category 2. With this letter, we would like to share some of civil society's perspectives in the hope that they can be taken into consideration in your country's reflection and written comments to be provided to the European Commission by 13 July.

The treatment of the TiO_2 dossier requires careful consideration of many, sometimes opposing, but similarly important elements. Whether in 'bulk' or in nano forms, TiO_2 is a substance used in a vast number of products currently on the EU market, in almost all sectors or product categories. The classification decision will therefore impact many sectors and lead to an obligation to label products containing TiO_2 with the appropriate CLP hazard icon and statements.

In order to adequately consider the various arguments put forward in this discussion, it is key to go back to the origin of the proposal. Given industry's decision to register TiO_2 as a single substance, i.e. with no distinctions between the 'bulk' and nano forms, or between different nano forms, the substance rightfully underwent a group dossier evaluation. ECHA's requests for further information from the substance registrant to be able to distinguish between different nano-forms of the substance (and its consequent proof of safe use) were met with systematic refusal and an action before the ECHA Board of Appeal to ensure that all forms of TiO_2 be considered as a unique substance with unique characteristics.

The consideration of all forms of TiO_2 for classification is therefore the result of a deliberate strategy by the registrants to refuse the differentiation between various forms of the substance.

In strict compliance with the procedures set out in REACH and CLP and coherence with the information submitted by the registrants, France then evaluated all forms of TiO_2 as one single substance, leading to ECHA's Risk Assessment Committee (RAC) opinion on the hazard classification of all forms of TiO2 as a carcinogen category 2 (i.e. suspected human carcinogen) through inhalation. There is no question that this opinion is science- and evidence-based, and properly adopted (by consensus) on the basis of a strict legal procedure and available information. The legality and substance of the arguments put forward to diverge from that RAC opinion should therefore be scrupulously scrutinised.

It is critical to note, in that respect, that the decision at hand is about substance classification and labelling, not about restriction or risk management measures. Such a decision must follow a clear legal process based on hazard assessment and identification. The current process has meticulously complied with legal requirements while most of the arguments currently put forward subsequent to the RAC opinion are based on socio-economic considerations. Taking these arguments into account to diverge from the RAC opinion would create a precedent that would put in jeopardy the carefully established balance of CLP. It would furthermore open the possibility of a legal challenge to the decision, creating further legal uncertainty and further mobilising important public resources.

We therefore believe that the European Commission's and the Slovenia/UK proposals to derogate from RAC's science-based opinion, to classify only powder forms or to exclude particle toxicity and/or the liquid form from the CLP's scope would disregard important factual elements, would depart from science- and evidence-based processes, would set a dangerous precedent, and could possibly be considered illegal.

Neither of the proposals respects the existing legislative framework or the corresponding procedures for its implementation. Furthermore, there is no scientific evidence that the liquid form of TiO_2 does not potentially cause cancer (for example by inhalation exposure of other forms of TiO_2 such as liquid form through aerosols). Therefore, we do not see any valid or acceptable reason to exclude any form of TiO_2 from being classified as a suspected carcinogen as recommended by RAC.

Having said this, strictly adhering to science-based and evidence-based decision making in following the RAC opinion does not preclude further refinement of classification in future, should the revised REACH Annexes result in the provision by industry of more refined scientific information on certain forms of TiO_2.

In communicating our view, we appreciate the significance of the impacts of classification and labelling of a substance as widely used as TiO_2. However, we believe that the carefully established balance of REACH and CLP processes and procedures have been established to guarantee fair consideration of all arguments in a science-based process. This careful balance would be seriously jeopardised by the adoption of the Commission proposal in that respect. Furthermore, we anticipate that ignoring science to privilege the business-as-usual operations of certain economic actors in violation of the rule of law will not be appreciated by a public that already has doubts about the European institutions commitment to protect its citizens and environment. We further note that, should additional scientific information be provided in the context of the implementation of the revised REACH annexes, this classification decision can always be revised without endangering our carefully established science-based regulatory framework.

We therefore urge you to uphold the rule of law and science-based decision making by supporting the full implementation of RAC's opinion for the classification of all forms of TiO2.

Yours sincerely,

Jeremy Wates
Secretary General

On behalf of:

Agir pour l'environnement
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France Nature Environnement (FNE)
Friends of the Earth Australia
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