To: Members of the REACH Committee

Brussels, 6 June 2018

Dear Sir/Madam,

We are writing to you regarding the REACH Committee Meeting that will take place next week on 13 June. At this meeting a crucial discussion on the classification of titanium dioxide (Ti02) as carcinogen category 2 will take place under the agenda item "Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Inclusion in Annex VI of RAC opinions of 2017 – 14th ATP)."

We are deeply concerned by the discussions taking place regarding the classification of TiO_2: an unprecedented lobby by the TiO2 manufacturers and downstream users is deviating from the CLP regulation's purely scientific endeavour to include socio-economic considerations such as market consequences of the decision, impact on the circular economy, perceptions, claimed lack of alternatives and even the indispensable 'bright colours' it provides.

Moreover, risk and exposure aspects are being considered in this process. As stated in Recital 10 of the CLP Regulation No 1272/2008 and recalled by RAC, the classification is based solely on the (intrinsic) hazardous properties of the substance. It does not take into account the likelihood of exposure to the substance and therefore does not address the risks of exposure.

The CLP process is a scientific hazard-based process where there is no room for these misleading risk or political considerations.

It is also worrying to see a proposed derogation for the classification of TiO2 in liquid form, even for liquid mixtures that can/are meant to be sprayed and therefore may be inhaled, and potentially cause cancer. We would like to emphasize that such derogation is not supported by robust scientific data that demonstrates that a sprayed liquid or solid matrices containing TiO2 will undoubtedly not cause cancer. On the contrary it seems logical that spray particles can in fact be very easily inhaled. For example, if paint is being sprayed, the possibility of intoxication by inhalation remains.

In September 2017 ECHA's Risk Assessment Committee (RAC) delivered their opinion on the hazard classification of **all forms of TiO2**, proposing a classification as a carcinogen category 2 (i.e. suspected human carcinogen) through inhalation. At ECHA's opinion, there is no reference at all to either powder or liquid form of TiO2, indeed the proposed classification applies to the overall chemical substance:

> ***"To ensure that all relevant scientific and regulatory aspects are taken into account RAC proposes the following scope of an entry in Annex VI of CLP: "Titanium dioxide" (without a further physico-chemical description) is proposed to be used as chemical name (international chemical identification). The CAS number to be used is 13463-67-7... The EC/CAS inventory listing for Titanium dioxide (236-675-5/13463-67-7) covers any chemical that has "TiO2" as its molecular formula and is therefore the broadest possible identifier for TiO2 chemicals***."

As the dossier submitter concluded in its harmonised classification and labelling proposal, since the data provided [by the registrant] cannot distinguish whether a specific form of TiO2 is linked to its toxic effect, this classification should be applied to "titanium dioxide in all phases and phase combinations; particles in all sizes/morphologies". The description of tested TiO2 is not explicit concerning the shape of the primary particles. Yet, when a chemical is classified, this classification must be translated into labelling to inform both workers and consumers.

Furthermore, as acknowledged by RAC, **TiO2 lung carcinogenicity is associated with inhalation of respirable TiO2 particles**. For this reason, RAC considers the toxicity profile observed as a basic property of inhaled and respirable particles of TiO2. Hence, **from a toxicological point of view (following the CLP regulation criteria) all inhalable forms of TiO2 deserve a classification as carcinogen category 2 at the least**.

In that respect, we believe that the **RAC's opinion on classification of TiO2 should be followed and any derogation or limitation to the classification of TiO2 (including size based separate entries or size threshold) would have no scientific, legal or ethical justification whatsoever and should therefore be firmly rejected.**

Supporting civil society organizations further acknowledge that some of the questions raised by TiO2 classification are relevant for the classification of other Poorly Soluble Low Toxicity (PSLT) particles. **We call on the competent authorities to act and propose without delay risk management measures to protect citizens from exposure to all Poorly Soluble Low Toxicity (PSLT) Particles.**

It is worth bearing in mind that **the classification of CMRs category 2 does NOT trigger any restriction as implied by industry stakeholders. Harmonised classification under CLP regulation ensures information provided to workers and consumers, so labelling is the minimal measure to ensure health protection the authorities should put in place**.

We also note some arguments that workers are already protected through occupational health legislation and derived OELs and that consumers are not exposed. This is not true. **There is extensive evidence that OELs are not protective for the nano forms and freelancers and artists are not covered by occupational legislation in the EU**. As an example, spray paints widely used by consumers without any protection may not be classified as carcinogens although according to ECHA, inhalation of TiO2 may cause cancer. Similarly, consumers broadly using spray sunscreens containing

TiO2 will be unnecessarily put at risk without any information being provided to ensure protection from cancer risk.

For this reason, **as a complementary measure to the harmonised classification and labelling as carcinogen category 2, we call on the European competent authorities to propose without delay a restriction of the use of Ti02 in consumer articles based on a simplified procedure (REACH article 68(2)).**

Finally, if the competent authorities do not follow ECHA's opinion, a very bad precedent will be set as competent authorities will open the door for disregarding science in future.

Yours faithfully,

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Senior policy officer - Chemicals and nanotechnology

On behalf of:

ECOS
European Environmental Bureau (EEB)
HEAL

In view of the public interest in this matter, we intend to make this letter publicly available.