To: Members of the REACH Committee

Brussels, 8 February 2019

Dear Sir/Madam,

We are writing to you regarding the REACH Committee Meeting that will take place on the 14 and 15 of February 2019. At this meeting crucial discussions, and potentially votes, are
planned on a large number of classification and labelling, restriction and authorisation proposals, including very broad applications for authorisation that, if granted, will allow the continued exposure of thousands of European citizens and the environment to substances of very high concern.

For discussion and tentative vote:

1) 14th ATP of CLP including Titanium Dioxide
2) authorisation for a use of chromium trioxide (Gerhardi Kunststofftechnik GmbH)
3) authorisation for certain uses of chromium trioxide (Lanxess Deutschland GmbH and others)

For (preliminary) discussion:

4) restriction of lead and its compounds in PVC
5) restriction of lead in gunshot in wetlands
6) derogation to the restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (AstraZeneca)
7) authorisation for certain uses of DEHP in PVC (DEZA a.s.)
8) review of an authorisation for certain uses of DEHP in recycled (Plastic Planet s.r.l.)
9) authorisation for certain uses of chromium trioxide (HAPOC GmbH & Co KG - 1, 2 and 3)

Titanium Dioxide Classification

This topic has been under discussion for a number of REACH committee meetings, following a valid substance evaluation process by France, and a scientifically justified opinion of the Risk Assessment Committee suggesting the classification of all forms of Titanium Dioxide as a carcinogen category 2. Because of the nature of the proposed decision, it is important to stress that both these processes scrupulously adhered to legal and scientific standards and applicable legal rules.

However, for the first time in CLP history, the classification proposal up for decision proposes to derogate from the RAC proposal by restricting the classification proposal to only certain forms of TiO2, in contradiction to the choice made by the registrant to register TiO2 as a single substance regardless of form, and both the substance evaluation performed by a Member State (France) and the RAC process.

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 put forward to derogate from the RAC opinion are based on socio-economic considerations that have no place in the classification discussion. 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.

The European Commission’s proposal to classify only powder forms or only particles above a certain size, and 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.

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

Unacceptably broad applications

We are deeply concerned about the proposal to grant authorisation to two extremely broad applications for the continued use of DEHP in virgin PVC (DEZA) and chromium trioxide (Lanxess). These two applications are the perfect examples of applications that must be rejected in application of Article 60 of REACH.

- The uses applied for are extremely broad, covering the use of thousands of tonnes of these substances of very high concern, in whole industrial sectors with hundreds of different downstream users using different processes.
- RAC considers that the uses of these chemicals pose a health risk to thousands of workers throughout Europe.
- The uses are not well defined, therefore information that is key for the risk assessment such as the exposure data is so deficient that it does not allow to assess the risk adequately according to RAC.
- The wide definition of the uses applied for are also disconnected from the analysis of alternatives, in contradiction with the ECHA guidance on the description of use,¹ and the spirit of the authorisation process to encourage and reward substitution.
- For the Lanxess application, the Commission proposes, as a remedy to this, in essence, to leave the definition of the scope of the authorisation to Member States enforcement authorities.
- Applicants do not demonstrate that alternatives are not available for all the uses covered in the application.
- The socio economic analyses provided by the applicants have high deficiencies that lead to underestimate the benefits for society of stopping the use of these chemicals.

Moreover, a decision on the DEZA application is long overdue and the applicant has already benefited from several years of de facto authorisation despite RAC concluding already in January 2015, that the data provided on the exposure was not adequate.

During the last five years there has been a wide discussion on how to avoid these types of broad upstream applications for authorisation (AfA) being submitted and granted authorisation, including a resolution from the Parliament, discussions at CARACAL, ECHA MB, and numerous workshops organised by ECHA and Member States. In fact, several downstream companies covered by the broad Lanxess application to continue using sodium chromate have submitted an AfA for their specific use.

In earlier letters to you\(^2\) we have provided details on why these applications do not comply with REACH legal requirements for granting authorisations.

We are also concerned about the proposal to grant authorisation to applications where other European companies have shown the availability of safer alternatives, as is the case of the AfA submitted by Gerhardi to continue the use of chromium trioxide.

The Plastic Planet case will also set a precedent on how review reports are assessed, and in which circumstances an authorisation could be withdrawn. This case thus requires careful attention.

Bearing in mind the upcoming elections, the REACH Committee now has the opportunity to reject these applications that hamper the potential of REACH to protect people and the environment and to promote innovation for safer alternatives.

**The REACH Committee will also discuss the proposals to restrict lead and its compounds in PVC and in gunshot in wetlands**

We strongly support these restriction proposals which will reduce emissions of this highly toxic chemical to the environment. However, we vehemently reject the proposed derogations that would allow much higher concentrations of lead in recycled materials (1%) compared to virgin material (0.1%).

The EU has embarked on a move towards a circular economy. It is therefore critical to prevent hazardous substances like lead from entering the supply chain in the first place. The proposed derogation will allow for continued contamination of the supply chain and consumer products far into the future, greatly weakening the effect of the restriction and undermining public trust and support to recycling.

We recall that the **Council Conclusions** of 25 June 2018 on the options to address the interface between chemical, product and waste legislation “strongly highlight the importance for establishing non-toxic material cycles”. This should also concern eco-innovation achieving the detoxification of waste containing legacy substances, which is already possible for lead contained in recycled materials like PVC. In addition the related **Parliament resolution** “[r]eiterate[d] that in accordance with the waste hierarchy, prevention takes priority over recycling and that, accordingly, recycling should not justify the perpetuation of the use of hazardous legacy substances”.

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Not restriction but derogation for PFOA

Finally, we ask you to reject the Commission’s proposal to approve a derogation to the restriction of PFOA in order to allow the pharma company AstraZeneca to continue use of a likely persistent, bioaccumulative substance (PFOB) contaminated with a PFOA-related substance (PFOI) which is predicted to become an Arctic contaminant and appears to be an endocrine disruptor. Although alternatives are widely available, AstraZeneca’s primary argument for a REACH derogation is that a search for alternative processing substances would entail extra time and cost. They propose instead to weaken the REACH PFOA regulation which is supposed to protect the health and environment\(^3\). Moreover, PFOA will be included under Stockholm Convention with much stricter exemptions compared to REACH.

Therefore we ask you to:

1. Reject the Commission proposal to restrict the classification of TiO2 to only a limited number of forms, as carcinogen category 2, in contradiction with the RAC opinion.

2. Reject the authorisation for the use of DEHP in PVC consumer articles based on REACH Article 60 paragraphs 2 and 4.

3. Reject the authorisation for certain uses of chromium trioxide (Lanxess Deutschland GmbH and others) based on REACH Article 60 paragraphs 2 and 4.

4. Reject the authorisation of chromium trioxide for the Gerhardi application.

5. In application of Article 61 of REACH withdraw the authorisation held by Plastic Planet.

6. Support the restriction of lead in gunshot in wetlands.

7. Support the restriction of lead and its compounds in PVC, and reject the derogation that allows high levels of lead in recycled materials.

8. Reject the proposed derogation to the restriction of PFOA in order allow Astra Zeneca the continued use of PFOA related chemicals.

\(^3\) EEB and IPEN Comments on the Request for additional derogation to Entry 68 of Annex XVII of REACH for PFOA. August 2018
Yours faithfully,

[Signature]

Tatiana Santos Otero
Policy Manager - Chemicals and nanotechnology, European Environmental Bureau

On behalf of:

Agir pour l'environnement (France)
ALHem - Safer Chemicals Alternative (Serbia)
AWHHE - Armenian Women for Health and Healthy Environment (Armenia)
Breast Cancer UK (UK)
BUND - Friends of the Earth Germany (Germany)
CIEL - Center for International Environmental Law
ClientEarth
Danish Consumer Council (Denmark)
Danish Ecological Council (Denmark)
ECOCITY (Greece)
Ecologistas en Acción (Spain)
ECOS - European Environmental Citizens Organisation for Standardisation
EEB - European Environmental Bureau
Federation SEPANSO (France)
Générations futures (France)
HCWH Europe – Health Care Without Harm Europe
HEAL - Health and Environment Alliance
HEJSupport International
Hogar sin Tóxicos - Fundación Vivo Sano (Spain)
IPEN
Seas at Risk
Society for Earth - Towarzystwo na rzecz Ziemi (Poland)
Surfrider Europe
Swedish Society for Nature Conservation – SSNC (Sweden)
WECAF - Women Engage for a Common Future
WEN - Women's Environmental Network (UK)
ZERO – Associação Sistema Terrestre Sustentável (Portugal)
Zero Waste Europe

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