To: Members of the REACH Committee

Brussels, Tuesday 9 April 2019

Dear Sir/Madam,

We are writing to you regarding the **REACH Committee Meeting that will take place on 11 and 12 April 2019**. At this meeting a **discussion to analyse the General Court Judgment T-837/16 and consequences on draft authorisations** and a discussion with a potential vote on the **classification of titanium dioxide** (14th ATP -CLP Session) are foreseen.

Analysis of Court Judgement T-837/16 and consequences on draft authorisation decisions still to be decided

We welcome the initiative to dedicate a lengthy discussion to the analysis of the Judgment T-837-16 (the General Court in Sweden vs Commission) and its consequences on pending draft authorisation decisions. We believe that this judgment has strong implications on the interpretation of the REACH authorisation provisions.

We hereby wish to stress several non-exhaustive points of the judgment that we trust deserve particular attention from the Commission and members of the REACH Committee as they must be applied to future authorisation decisions: the burden of proof on the applicant, the Commission's responsibility to ensure

that the Authorisation provisions are met, and general interpretation of Authorisation provisions. We detail the consequences of the judgment on specific draft authorisation decisions still to be decided in the Annex.

We also highlight recent European Parliament objections[1] to three draft implementing acts relating to proposals for authorisation decisions, which were interpreted in light of this judgment.

I. The burden of proof is on the applicant

The judgment of the General Court recalls that the applicant has an obligation to prove the absence of suitable alternatives according to Article 60(4) of REACH. This obligation also implies that the applicant bears the risks of the determination of whether alternatives are available (paragraph 79).

If uncertainties remain as regards the availability of suitable alternatives, then the applicant has not fulfilled its obligation and the authorisation cannot be granted. On the contrary, the judgment also specifically states that no actor in the procedure has to demonstrate that alternatives actually exist (paragraph 79).

II. The Commission has the responsibility to ensure that the conditions for authorisation are met

The judgment points out the active responsibility of the Commission in ensuring that the conditions for authorisation are effectively met, in line with the principles of good administration and due diligence (paragraph 64).

As regards the opinions of the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC), the Commission must take them into account and verify their completeness, coherence and pertinence of the reasoning. In this context, the Commission can choose to either follow the Committees' opinions or depart from them as the Committees' opinions constitute scientific advice. However, in case the Commission chooses to depart from one of the Committees' opinions, it must comply with a certain number of conditions, including demonstrating a serious doubt over the Committees' opinions in question, specific motivation, an equivalent scientific level of evidence, it may also require another opinion from the committees or base its conclusion on other solid scientific basis (paragraphs 66 to 69).

Given its active responsibility, the Commission cannot solely rely on the applicant's arguments as regards the assessment of alternatives and must soundly scrutinise, by its own means, the information needed to

[1] European Parliament, resolution of 27 March 2019 on the draft Commission implementing decision granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others) available here;
European Parliament, resolution of 27 March 2019 on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.) available here;
European Parliament, resolution of 27 March 2019 on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.), available here;

take a decision. This includes, but it is not limited to, information from ECHA's committees, information provided by third parties or Member States, or information gathered by the Commission from its own motion (paragraphs 79, 85, 101).

In the event where the information received or requested has not clarified uncertainties regarding the scientific assessment of the unavailability of alternatives, the Commission is not entitled to grant an authorisation (paragraph 85).

III. General interpretation of the authorisation provisions

Where substantial conditions of Article 60(4) are not met in the first place, the authorisation procedure cannot be subject to conditions to remedy the deficiencies of the application, nor can it be subject to an assessment in the light of the proportionality principle (paragraphs 83 and 102).

In light of the developments of the judgment, the General Court reminds that REACH aims to ensure a high level of protection of human health.

We expect members of the REACH Committee to duly reflect on the consequences of the judgment in order to adapt future authorisation decisions accordingly. We include some examples of draft authorisations that should be impacted by the judgment of the General Court in annex.

Classification of titanium dioxide under the 14th ATP of CLP Regulation

As stated in our latest collective letter, dated 1 March, and previous letters (1, 2), the classification of titanium dioxide (TiO_2), already discussed in a number of REACH committee meetings, has been greatly undermined compared to the original proposal made by France or the recommendation by ECHA. This follows from a valid substance evaluation process by France and a scientifically justified opinion of the Risk Assessment Committee, which recommends the classification of all forms of Titanium Dioxide as a category 2 carcinogen by inhalation. Because of the nature of the proposed decision, it is important to stress that both these processes scrupulously adhered to scientific standards as well as applicable legal rules. This is not only in contradiction with the choice made by the registrant to register TiO_2 as a single substance regardless of forms, but also with France's consequent substance evaluation, the RAC opinion and established legal rules.

However, for the first time in the history of the CLP regulation, the classification proposal to be voted upon suggests to deviate and derogate from the RAC proposal. This deviation from the ECHA's opinion would also impact the rules applicable to waste containing classified substances as hazardous by restricting the classification proposal to only certain forms and sizes of TiO_2. The Commission not only introduced a limitation to the classification and labelling of titanium dioxide to the powder form, but also to the respirable particles size (instead of the inhalable size). It also introduced a derogation for mixtures, despite CLP requiring that all mixtures containing a hazardous classified substance above a certain concentration must be classified and labelled accordingly. There is no scientific justification to support such deviation from

ECHA's opinion or to derogate the classification of mixtures procedure. Nevertheless, the Commission's draft decision will prevent potentially carcinogenic substances, mixtures, materials and waste from being classified and labelled accordingly. This will greatly undermine the proper risk management of mixtures and materials necessary to protect human health.

Over the last weeks, a number of media reports have relayed that the Commission is drafting an updated guidance document that would further deviate from the waste classification rules as well as restrict the reach of the classification decision by derogating to the existing rules applicable to waste of classified substances. Should these reports be true, we highly regret the lack of transparency of this process, in which stakeholders were not given the opportunity to make comments. Moreover, these amendments are limited to "normal" conditions of use and materials, but they disregard other recovery processes that may place workers at risk during for example heating or cutting of materials, which would involve potential exposure to powder or liquid droplets of TiO_2.

We also believe that the Commission is not entitled to substantially change the waste classification rules, merely in order to accommodate the TiO_2 industry's needs, without proper scientific justification, rather than the claimed economic impact to users or producers. This change would set a very worrisome precedent for all chemicals to be classified in the future, beyond TiO_2.

Finally, the "updates" contained in the proposed guidance imply crucial aspects (such as risk-based elements in the waste classification process or bioavailability criteria) that are still under discussion under the interface between chemicals, products and waste legislations. This creates a lack of coherence of the different regulatory frameworks and a lack of predictability for stakeholders impacted by the document. This also risks undermining the proper risk management of mixtures and materials necessary to protect human health, in particular workers at the waste management and recycling facilities that will not even know about the potential carcinogen in the materials they are dealing with and exposed to.

The decision at hand is about a substance classification, labelling and packaging, not its restriction. As we have already stressed on a number of occasions, such a decision must follow a clear legal process based on intrinsic hazard identification and assessment. To date, the process has meticulously complied with legal requirements, whereas 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 would create a precedent that would endanger the carefully established balance of CLP. It would also open the possibility of a legal challenge to the decision, adding legal uncertainties and further mobilising important public resources. Moreover, the Commission's draft decision to be voted next week derogates, without proper scientific justification, potentially carcinogenic substances, mixtures, materials and waste. This means that mixtures and materials, such as sprayed liquids/solutions or even some inhalable particles, will not be classified or labelled as being suspected carcinogenic although they can potentially cause cancer. Consequently, the new proposal to amend the guidance on waste classification would create a further precedent allowing waste containing a classified substance to be treated as if it were not.

The European Commission's proposal to classify and label only powder forms or only particles above a certain size, and to exclude mixtures classification and labelling from the CLP's scope would disregard

important factual elements, depart from science- and evidence- based processes as well as from the letter of the law with regard to mixtures classification, labelling and packaging. It would also set a dangerous precedent and could possibly be considered illegal. In addition, inserting guidance to specifically derogate from existing rules applicable to waste containing classified substances would create legal uncertainty and represent yet another dangerous precedent to derogate from existing legislation protecting the health of workers and the environment for the sake of industry's profits.

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 TiO_2;**
- **postpone discussion on the development of guidance on waste classification until a conclusion is reached on the interface between chemical, product and waste legislations. We believe that this guidance should be subject to a stakeholder consultation.**

Yours faithfully,

Tatiana Santos Otero

Policy Manager- Chemicals and nanotechnology, European Environmental Bureau

On behalf of:

European Environmental Bureau (EEB)
Center for International Environmental Law (CIEL)
Safe Food Advocacy Europe (SAFE)
Women in Europe for a Common Future (WECF)
Health and Environment Alliance (HEAL)

Annex

Consequences of the judgment on specific draft authorisation decisions still to be decided

I. The burden of proof is on the applicant

- Specific applications for authorisation to use DEHP in the production of PVC articles: in several cases, SEAC concludes that the applicants did not demonstrate that alternatives were not available for the use applied for, casting serious doubts over the unavailability of alternatives. This applies for instance to the applications for authorisations of Grupa Azoty ZAK S.A and the technical feasibility of alternatives[2]. and DEZA a. s.
- Applications for authorisation to use chromium trioxide: SEAC has already concluded that it could not exclude possible uncertainty with regard to the technical feasibility of alternatives for a limited number of specific applications that are covered by the description of the uses applied for[3]. This applies for instance to applications for authorisations from Lanxess Deutschland GmbH.

II. The Commission has a responsibility to ensure that the conditions for authorisation are met

- Specific applications for authorisation to use DEHP in the production of PVC articles: in the case of the Grupa Azoty ZAK S.A. and Deza a.s. applications, the applicants have announced[4,5] that they ceased production of phthalate plasticisers or shifting production to "safer" phthalates. The Commission can, on its own initiative, use the information displayed on the applicant's website to assess the suitability of alternatives in that case.
- Applications for authorisation to use chromium VI: third parties have provided information raising uncertainties as regards the unavailability of alternatives to chromium VI[6]. This should impact the applications for authorisation such as those of HAPOC GmbH & Co KG, Lanxess Deutschland GmbH.

III. General interpretation of authorisation provisions

- Applications for authorisation to use chromium VI: appropriate exposure scenarios represent a substantial condition of the exposure assessment according to paragraphs 6.1 to 6.5 of the REACH Annex I, hence to an application for authorisation. In the case of the application for authorisation to use chromium trioxide (for functional chrome plating with decorative character)

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[2] SEAC Opinion, pages 14 and 15
[3] SEAC Opinion, page 40
[4] Grupa Azoty ZAK S.A. focused on non-phthalate plasticizers, 27 February 2018
[5] TV investigation by Jan Tuna
[6] Alliance of PVD Providers, Manifest, *A sustainable alternative to CrVI*

by Lanxess, RAC requires that an appropriate exposure scenario is developed, indicating that such essential conditions are not yet met.