To: Members of the REACH Committee

Brussels, 1 March 2019

Dear Madam/Sir,

Following on several civil society letters, we are writing to you again regarding the REACH Committee meeting that will take place next week (7 March). Several crucial (preliminary) discussions and potential votes of concern for civil society groups are planned:

(1) The decisions to (partially) grant an authorisation under the REACH Regulation to (among other uses) produce PVC articles of bis(2-ethylhexyl) phthalate (DEHP) to Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s.

(2) The 14th ATP of CLP including Titanium Dioxide

1. The decision for (partially) granting an authorisation to produce PVC articles of DEHP

The undersigned civil society groups firmly reject the authorisations of DEHP used to produce PVC articles. **Granting an authorisation for these applications would be in breach of the provisions of Title VII of REACH**, in particular Articles 60, 62 and 64 of REACH **and would undermine the key objective of this regulation**: "to encourage and [...] to ensure that substances of high concern are eventually replaced by less hazardous substances or technologies where suitable economically and technically viable alternatives are available" (Recital 12).

Although the Commission's proposal for a decision partially rejects these applications, it still allows, without adequate justifications, a substantial amount of DEHP for PVC production for an additional period of four years, and potentially many more as it is not clear in which circumstances the Commission will be in a position to legally withdraw the authorisation at the end of this period.

Granting these authorisations on the condition that the applicant provides, later on, in its review report the missing data in the original application, is in clear violation of Article 61 and 60. It amounts to granting a driver's licence, without requiring the person to pass the test, leaving it to the driver, later on, to prove it can drive safely. It is not only illegal, it is irresponsible in particular for the workers and the general public exposed to this substance every day.

This application is the perfect example of an application that must be fully rejected for the following reasons:

- **the risks related to the uses of DEHP are not adequately controlled;**
- **the applications are so broad that they cover the use of thousands of tonnes of this substance of very high concern, across an entire industrial sector with hundreds of different downstream users using different processes;**
- **the applicants failed to provide the necessary information**: 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 the Risk Assessment Committee - RAC);
- **the applicants failed to demonstrate that alternatives are not technically feasible** (according to the Socio-Economic Analysis Committee - SEAC);
- **the wide definition of the uses applied for are also disconnected from the analysis of alternatives**, which is in contradiction with the ECHA guidance on the description of use and the spirit of the authorisation process (meant to encourage and reward substitution);
- **there are serious procedural and substantive flaws of the DEHP in PVC opinions of RAC and SEAC.** In particular, **the public was denied the information necessary to contribute to the consultation[1] on alternatives as confirmed by the** judgment of the General Court in 2017;
- **the applicants have already benefited from several years of *de facto* authorisation (even longer than recommended by RAC and SEAC opinions);**

[1] e.g. 70% of the documentation included in the Deza application was deemed confidential

- **the circumstances have changed so much that the Commission's decision would be based on highly outdated scientific and economic information communicated by the applicants and ECHA's committees at the time of the application (2013)**; **Some developments (e.g. identification of DEHP as an endocrine disruptor) affect the assessment of the risk to human health and the environment and thus the socio-economic assessment; in addition, new information on possible substitutes became available;**

- there are currently no other companies producing DEHP in Europe, which illustrates that DEHP is no longer needed to produce PVC articles and **safer alternatives are available**;

- the applicant **Grupa Azoty ZAK S.A. has declared that it has already "ceased production of DEHP" and shifted to other alternatives. Moreover, the applicant Deza a.s. has also stated that they are substituting DEHP gradually and are shifting production to "safer" phthalates**.

- allowing these two companies to keep production of DEHP to be used in plastic consumer products means that **children, who are particularly vulnerable, will continue to be exposed to DEHP in plastic products**. Even though exposure to children should be reduced thanks to the phthalates restriction adopted in 2018, it is worth noting that this restriction provides for wide derogations and will likely have limits in practice. As a reminder, despite pre-existing restriction and of DEHP in toys:

    - **every fifth toy inspected by EU enforcement authorities contained high levels of restricted phthalates** (including DEHP). Indeed, enforcement authorities found that DEHP presence in plastic toys is the most common non-compliance case;

    - Most of plastic toys (250 out of 290) for which officials issued warnings last year were about illegal levels of DEHP, according to analysis of alerts sent via the EU rapid alert system Rapex.

    - In 2018, Customs officers destroyed in 2018 31,590 mainly plastic Chinese dolls they considered a "serious risk" to children due to illegal levels of phthalates (including DEHP).

- **DEHP has been identified as an endocrine disrupting chemical on the Candidate List**; these authorisations not only put the EU citizens' health at risk, but also the environment;

- **the authorisations would penalise competitors committed to innovative solutions and producing safer products in Europe.** In fact, parallel regulatory measures restricting the uses of DEHP (and other phthalates) have benefited to the applicants, which now benefit from a market monopoly to continue producing the substance of very high concern.

As can be clearly seen from the above, the decisions that you will take at the upcoming REACH committee meeting will substantially impact whether environmental and people's exposure to DEHP can be reduced - which is particularly critical for vulnerable groups, such as babies in the womb, new-borns and young children.

These decisions will also either comply with the spirit of the REACH law or contradict its main purpose.

Bearing in mind the upcoming European elections, it is even more important that the REACH Committee rejects these applications and demonstrates the full European commitment to protect people and the environment; to send a sign to companies that only well justified applications may have an authorisation granted; and to favour and promote innovation for safer alternatives by frontrunners instead facilitating production of SVHCs.

More details on each of the above points are provided in the annex to this letter.

2. <u>Titanium Dioxide Classification</u>

As stated in our previous joint letter sent on 8 February, the classification of titanium dioxide has been under discussion for a number of REACH committee meetings. 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 (TiO_2) 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 the history of the CLP Regulation, the classification proposal up for decision suggests derogating from the RAC proposal by restricting the classification proposal to only certain forms of TiO_2. 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 substance evaluation and the RAC opinion.

The decision at hand is about substance classification, labelling and packaging, not about restriction. As we have already stressed on a number of occasions, such a decision must follow a clear legal process based on hazard identification and assessment. 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 endanger the carefully established balance of CLP. Furthermore it would open the possibility of a legal challenge to the decision, adding legal uncertainties and further mobilising important public resources.

The European Commission's proposal to classify and label 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, depart from science -and evidence- based processes, 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 TiO_2.

Based on the above arguments, and in view of the weight that your decisions at the REACH Committee meeting will bear for the protection of human health and the environment, we call on you to:

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

(2) 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.

Yours faithfully,

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

On behalf of:

Agir pour l'environnement, France

Alliance for Cancer Prevention, United Kingdom

Arnika - Toxics and Waste Programme, Czech Republic

CIEL

ClientEarth

ECOCITY, Greece

Ecological Council, Denmark

Ecologistas en acción, Spain

European Environmental Bureau (EEB)

Fédération SEPANSO Aquitaine, France

Friends of the Earth Germany (BUND), Germany

Future in our Hands, Norway

Générations Futures, France

Health and Environment Alliance (HEAL)

Health and Environment Justice Support (HEJSupport)

Hogar sin Tóxicos - Fundación Vivo Sano, Spain

Institute for Sustainable Development, Slovenia

Women Engaged for a Common Future (WECF)

Women's Environmental Network (WEN)

ZERO – Associação Sistema Terrestre Sustentável, Portugal

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

Annex. Authorisations for the use of DEHP in PVC consumer articles

DEHP is a well-known substance of very high concern due to its toxicity for the reproductive system and as an endocrine disruptor. DEHP is a phthalate, a group of "gender-bending" chemicals which cause the males of species to become more female. These chemicals have disrupted the endocrine systems of wildlife and potentially of humans too. DEHP can cause breast and testicular cancers, birth malformations and infertility, to name just a few. Due to its endocrine disrupting properties, no safe exposure threshold can be derived with sufficient certainty for DEHP. Moreover, it is also a suspected carcinogen and a neuro and immune toxicant.

Environment, health, doctors, cancer prevention advocates and green chemistry professionals have come together with women's organizations, and medical organisations to strongly oppose the authorisation of the use of DEHP in PVC items on the grounds of toxicity and the significant and long-term health risks to humans. It is already restricted in toys and childcare articles under other EU regulations. However, children are still highly exposed to consumer products containing phthalates, such as textiles, footwear or car seats.

Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s. applied in 2013 for authorisation of the use of DEHP in soft PVC-containing articles and still today use and produce it. Granting authorisations for these applications would not be in keeping with the provisions of Title VII of REACH, in particular Articles 60, 62 and 64 of REACH and would undermine the main objective of REACH "to encourage and [...] to ensure that substances of high concern are eventually replaced by less hazardous substances or technologies where suitable economically and technically viable alternatives are available".

Although the Commission's decision proposal partially rejects these applications, by:

- Refusing to grant the authorisation *fully* for "use 3": it proposes to exclude the capacitors because "no data were provided in the application" (nevertheless this is not a full rejection since it still grants authorisation for the rest of use 3 i.e. lambda sensor elements)

- Narrowing down "use 2" by excluding from the scope PVC articles covered by the new restriction

However, the Commission's proposal still allows major uses of DEHP:

- Trying to remedy deficiencies in the information provided by the applicant by proposing a "short" (4 years) review period => even though it is not clear in which circumstances the Commission will be legally in a position to withdraw the authorisation at the end of this period; and,

- asking the applicant to provide the missing data (that should have been provided in the application itself) in its review report => this amounts to granting a driver's licence without verifying if the person can drive and simply ask the person to prove, in 4 years, that he/she can actually drive.

The deficient information relates to:

- worker exposure in uses 1 and 2 (see §14-17): including information as fundamental as "workplace exposure"

- information on the analysis of alternatives for uses 1 and 2 (see §18): including the description of use 2 being too vague.

The undersigned organisations would like to remind the European authorities that:

The risks related to the uses of DEHP are not adequately controlled as RAC has clearly stated in its opinion.

There are suitable alternative substances and technologies. As highlighted in the SEAC's opinion, the applicants, when providing their analysis of alternatives, ignored alternative materials, substances and techniques claiming that they cannot produce the alternatives, even though authorisation is sought for many downstream uses, not for manufacturing.

Furthermore, DEHP has, to a large extent, already been replaced by other plasticisers and materials. During the public consultation, manufacturers of alternatives as well as downstream users applying these alternatives have provided overwhelming information which shows that readily available and technically and economically feasible alternatives do exist.

The applicants could not demonstrate that the socio-economic benefits of continued use outweigh the risk to human health or the environment. SEAC's opinion confirms that there were significant deficiencies in the socio-economic analysis presented by the applicants, including the lack of any health impact assessment identifying the remaining risk to workers' health.

Therefore, the legal requirements of Article 60(2) and 60(4) are not met and the authorisations must not be granted.

We are deeply concerned about the proposal to grant authorisation to these **extremely broad applications**, covering the use of thousands of tonnes of this substance of very high concern, in whole industrial sector with hundreds of different downstream users using different processes.

Consequently,

- 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, and the spirit of the authorisation process to encourage and reward substitution.

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 Management Board, and numerous workshops organised by ECHA and Member States.

Moreover, a decision on these applications is long overdue and the applicants have already benefited from several years of *de facto* authorisation (even longer than recommended by ECHA) despite RAC concluding already in January 2015, that the data provided on the exposure was not adequate. We regret the **long unjustified delay** of this particular decision that allowed these companies to keep placing this SVHC into the EU market pending the final authorisation decision, hence exposing our citizens and our environment despite DEHP's "sunset date" was the 21st January 2015.

Meanwhile, Grupa Azoty ZAK S.A. and Deza a.s. have declared that it has ceased production of DEHP and shifted to alternatives, therefore obviously proving the availability of alternatives (while in their applications they claimed they did not produce the alternatives as a justification for alternatives not being suitable). It therefore makes no sense to grant this authorisation.

There are currently no other companies producing DEHP in Europe, which show that DEHP is no longer needed to produce PVC articles and **safer alternatives are available**. Allowing Deza and Azoty to keep production of DEHP to be used in plastic consumer products not only put at risk the EU citizens' health but also **penalise the competitors producing safer products in Europe**.

Finally, we would like the EU authorities to take into account the **procedural and substantive flaws of the DEHP in PVC opinions by RAC and SEAC.** In particular, **the public was denied the information necessary to contribute to the consultation on alternatives as confirmed by the** judgment of the General Court in 2017: **The opportunity for third party input (according to Articles 64 (2) and (3)) was jeopardised by the lack of adequate access to relevant information**. There was no possibility of constructive third-party input because **70% of the documentation included in the Deza application was deemed confidential,** including the whole of the chemical safety report. Therefore, information essential for the submission of information on alternatives, such as the population exposed and import and manufacturing volumes, was not made available to third parties during the public consultation. Without the opportunity for third party input, the Commission would effectively not be able to comply with Article 60(4), second sentence, which stipulates that the authorisation decision shall be taken after consideration of all stated elements, including third party contributions submitted under Article 64(2). This should be acknowledged by the authorities what taking its decision.

These companies have been using DEHP after the sunset date in 2015. Even though the Commission states it "take[s] into account the new available information from the restriction process" (§3), it still didn't take into account the fact that DEHP has been recognised since the application for authorisation as an endocrine disruptor (which was already highlighted in the 2015 EP resolution). We consider that this factor ought to have been considered by the authorities together with the availability of safer alternatives; otherwise, **the Commission's decision would be based on highly outdated scientific and economic information** communicated by the applicants and ECHA's committees at the time of the application (2013).

The circumstances have changed so much as to affect the risk to human health or the environment and new information on possible substitutes became available. Therefore, these authorisations should not be granted.

Children that are particularly vulnerable are currently highly exposed to DEHP in plastic products.

In an EU/EEA-wide project of ECHA's Enforcement Forum, inspectors found hundreds of consumer products with illegal amounts of restricted chemicals. Every fifth toy inspected contained high levels of restricted phthalates (including DEHP).

The top one breach was phthalates in toys (20 % of inspected toys contained Bis(2-ethylhexyl) (DEHP), Dibutyl phthalate (DBP) or Benzyl butyl phthalate (BBP) at levels above those permitted).

Officials in 2018 issued warnings about 290 toys found with illegal levels of DEHP among other banned phthalates. Most (250) were plastic toys, 150 were plastic dolls. More toys failed chemical checks than any other type of product, including clothing (42), cosmetics (91), jewellery (51) and even protective equipment (5), according to analysis of alerts sent via the EU rapid alert system Rapex.

Also last year, news emerged that customs officers destroyed 31,590 mainly plastic Chinese dolls they considered a "serious risk" to children due to illegal levels of phthalates (including DEHP). Officers said 92% of the 722,000 toys seized carried the CE safety stamp.

Further information:

EEB Scorecard DEHP in PVC

Position paper: 55 EUROPEAN AND INTERNATIONAL CIVIL SOCIETY ORGANISATIONS ASK COMMISSION TO REJECT AUTHORISATION OF HAZARDOUS DEHP IN PVC PLASTIC

Letter to the European Commission November 2014: European and international civil society organisations ask Commission to reject authorisation of hazardous DEHP in PVC plastic

Letter to the European Commission January 2015: Procedural and substantive flaws of the DEHP in PVC opinions

Letter to REACH Committee January 2015: European civil society organisations ask Commission to reject authorisation of the substance of very high concern DEHP in PVC plastic

Letter to REACH Committee July 2018

Letter to REACH Committee September 2018

Letter to REACH Committee February 2019

EEB's report "A Roadmap to revitalise REACH"