OPEN LETTER

To: Mr Thierry Breton, Commissioner for the Internal Market

Cc: Mr Virginijus Sinkevičius, Commissioner for the Environment

European Commission, Rue de la Loi 200, Brussels

24th of March 2021

Subject: Need to act – judgment of the EU Court requires change of approach to chemical authorisation

Dear Commissioner Breton,

You will know more than anyone the importance of transforming the chemical industry to achieve the European Green Deal's goals, as the Commission recognised in the Chemicals Strategy for Sustainability. **We, the undersigned NGOs follow REACH implementation closely and are writing to draw your attention to a recent judgment of the Court of Justice that makes it clear DG GROW has misinterpreted key parts of EU chemicals law – when to authorise the use of the most hazardous substances.** The authorisation ruled illegal by the Court of Justice is not, unfortunately, a one-off mistake. It is the tip of the iceberg. This case is an illustration of the lenient policy the Commission has been applying in implementing the authorisation process of REACH, from the start. As DG GROW leads this work, we want to make sure you are aware of it, and we call for significant changes in the way authorisations for use of harmful chemicals are handled.

While we note that the Commission has learnt *some* lessons from this case since the judgment in first instance, by requesting new additional information ('substitution plans') to some applicants in ongoing cases, **much more needs to be done to avoid replicating the mistakes of the past.**

Under the REACH authorisation process, companies can apply for an authorisation to produce, import, sell or use substances of very high concern. These are the **most hazardous groups of substances that exist**: carcinogens, mutagens, reprotoxicants, and substances that are persistent, bioaccumulative, toxic and hormone disrupting, etc.

The REACH authorisation system is highly valuable since it has the potential to protect EU citizens and our environment from substances of very high concern as well as drive industry towards safe and sustainable chemistry – in line with the Chemical Strategy for Sustainability. Authorisation also puts the burden of proof on companies to show no suitable alternatives are available and that the societal benefits outweigh the risks. A report from ECHA

recently confirmed the authorisation requirement has positive effects on our health and the environment and has advanced substitution of harmful chemicals.

Unfortunately, the authorisation process has not delivered its full potential, mostly because DG GROW has led this work in violation of REACH for the last 10 years. The symptoms of a structural issue can be seen in Parliamentary resolutions against 6 authorisations[1], as well as in the decision by Sweden[2] and several NGOs including ChemSec, ClientEarth and EEB[3] to take the Commission to Court in the hope of stopping this practice.

The Court has now confirmed[4] what NGOs, the European Parliament and some Member States have been denouncing. This means the Commission needs to change its approach to respect the ruling of the Court. This will, in the longer run, mean a more efficient protection of EU citizens from harmful chemicals and a more effective signal to the industry to find substitutes for these substances of very high concern and to innovators to find safe and sustainable alternatives. It will bring the EU closer to achieving the ambitions in the Chemical Strategy for Sustainability.

We hope with this letter to have alerted you to the need for a change in the approach to REACH authorisation. We also hope we have convinced you about how important an effective authorisation process is to delivering the Chemical Strategy for Sustainability.

We remain at your disposal if you have any questions. In Annex 1 we have listed more specific examples of the issues encountered and the way forward.

Kind regards,

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[1] 25/11/2015, Vinyloop DEHP (in recycled PVC)- Adopted; 29/11/2018 Ormezzano Sodium Dichromate (wool dye) – Adopted ; 27/03/2019 DEZA DEHP (virgin PVC); 27/03/2019 Grupa DEHP (virgin PVC), 27/03/2019 LANXESS (now called Chemservices); Chromium VI; 24/10/2019 Cromomed Chromium VI

[2] Case T-837/16 Sweden v. Commission, ECLI:EU:T:2019:144

[3] Case T-437/17 ClientEarth, EEB, ChemSec, IPEN v. Commission.

[4] Case C-389/19 P Commission v. Sweden, Appeal of Case T-837/16, ECLI:EU:C:2021:131.

Annex 1

There are many applications for authorisation awaiting a Commission decision for which the applicants failed to bring strong evidence that the REACH conditions were fulfilled. Some will be discussed in the next REACH Committee (27-28 April). The time to recognise the errors of the past explicitly and start anew is now.

Examples of lessons from the Court that have not yet been explicitly accepted by DG GROW are the following:

1) If **non-negligible uncertainties remain, after** considering all available information including the applications, third-party information and opinions of ECHA's technical committees, **the Commission must reject the application[5].**

Many pending applications suffer from considerable data gaps, as is the case for the DEZA DEHP case, which has been awaiting a final decision for 6 years. Others suffer from uncertainties that remain as to the accuracy of the analysis of the applicant in light of third-party information. This is the case for the Ormezzano case, which has been pending for almost 4 years. The Commission must assume its role and reject those applications to ensure the effectiveness of REACH. It is important to note that as long as a decision is not taken, companies operate under a "de facto" authorisation. The data gap issue is not a problem of the past – the review reports that are now on ECHA's table suffer from the same weaknesses as the original applications.

2) **A non-negligible data gap or the presence of uncertainties is the applicant's failure.** No political or legal expedient in an authorisation decision can fix this. Recent proposals by the Commission show that it persists in past practice the Court has condemned, for example by:

- Asking for information that should have been submitted in the application after the authorisation is granted. This practice, recognised as illegal by the Court,[6] was repeated, for example, in the Cromomed authorisation in December 2020.[7]

- Transferring the task of identifying which uses respect REACH conditions to the users themselves, instead of exhaustively listing in the authorisation decision the uses for which the Commission has sufficient certainty that the conditions are fulfilled. The Court confirmed this practice was illegal[8] but is still used, for example when the Commission adopted its Chemservice decision (chromium VI), now challenged by the European Parliament, as well as the Commission's REACHLaw decision[9].

[5] See para. 32-34 of the judgment.
[6] See para. 45.
[7] C(2020)8798 Cromomed S.A OJ C 444 22.12.2020, p.4.
[8] See para. 44.
[9] C(2020) 8735 REACHLaw Ltd Annex OJ C 442 21.12.2020,p 5.

- Adopting a very restrictive view of what an acceptable alternative is, by accepting too easily applicants' claims that an alternative must have the same performance as the substance of high concern. The Court considered that this approach undermines the effectiveness of REACH[10], and rightly so as performance can be inferior but still acceptable for the end-use. A good example of this practice is the pending decision on Ormezzano (Sodium Dichromate), which should be rejected, and the pending decision on Gruppo Colle,[11] related to the same substance, which should likewise be withdrawn.

[10] Para. 56.
[11] C(2017)8331 Gruppo Colle.S.r.l OJ C 441 22.12.2017, p.15.