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Strengthen accountability Align REACH with best practices

The EU institutions and States spend considerable resources adopting protective chemical norms. If they are respected by all, then the effort for better protection is both more effective and shared more fairly amongst companies and Member State authorities.

But today, many can escape the rules because the accountability systems set by REACH are deficient. Discussions on the new REACH and enforcement currently focus on "enforceability", and the solution proposed is a more systematic involvement of the enforcement Forum. The Forum has been useful and will continue to be, but the issues behind the lack of enforcement will in no way be solved solely by broadening its role.

Therefore, we need to use REACH reform to address the issue of enforcement more holistically and bring to chemical law best practices from other areas EU law, i.e. the best safeguards adopted or proposed recently in areas such as the IED, consumer law, anti-discrimination law or GDPR. There is no reason the safeguards protecting people and the environment against toxic chemicals should be weaker than those that apply to our consumer choices.

Simple does it – create clear and specific obligations for companies

The measures that have been applied and enforced the most successfully are those that are clear, specific and mandatory. In practice this entails:

- Making the rules precise on who they target and what they must do. No or very little discretion is left to the companies as to the scope or content of their obligations because that gives legal certainty to the companies and the enforcement authorities. Some of the authorisations adopted today, making the companies in charge of checking whether they are covered, create enforcement nightmares for all.
- Creating a hierarchy of measures. For the most harmful substances, shift the default legal status of their production and use to illegal (as promised by the CSS). The EU Court, ruling on



chemical regulation, was clear: "A restriction on the placing on the market – including, in accordance with the definition in Article 3(12) of Regulation No 1907/2006, import – of a substance *is often the most effective measure for achieving the objective pursued* by that regulation, which is to ensure a high level of protection of human health and the environment".¹ Less effective and much harder to enforce actions (limit values, training, etc.) should only be considered on an exceptional basis.

The Forum could help by giving optional advice on the matter.

It takes a village – Multiply the enforcers

REACH has an exceptionally broad scope. Who is covered? Manufacturers, importers and users from any sectors. What is covered? All chemicals, and almost all uses. If we had enough enforcers, then REACH's impact would be multiplied.

But today we do not have enough enforcers for the job, because the work relies mostly on the Member States, who do not have equal resources to dedicate to this work; and partly on ECHA, which struggles with capacity.

Therefore, we need to drastically increase the resources spent on enforcement, by ensuring that all Members States are involved, and that they are not alone on the job.

Consistency across the Member States – add clear and common obligations on enforcement systems and activities

The enforcement systems built by the Member States and the activities they lead need to be harmonised – in line with the recommendations made by the High-Level Roundtable on the CSS in 2021.² REACH reform needs to develop a common approach, for example through criteria and standards against which the effectiveness of Member States' control systems can be assessed.

The commitment made under the CSS to establish under the Market Surveillance Regulation uniform conditions and frequency of checks for certain products - where specific risks or serious breaches of EU legislation have been continuously identified – is a step in the right direction.

The role of the Forum should be maintained and enhanced to support harmonisation of practices and common enforcement activities. The High-Level Roundtable's report provides useful insights on how to support that role (see Recommendation 4).

In order to ensure that the criteria and standards adopted are indeed implemented, we support the creation of an EU audit system, as promised by the CSS and discussed in CARACAL as option 1.

✓ Authorities cannot be everywhere – Enlist private parties

REACH 2 must include an explicit legal basis for ensuring critical transparency. ECHA has struggled with its own interpretation of REACH when it comes to key information needed by the public at

¹ T-226/18 Global Silicones Council and others v Commission, ECLI:EU;T:2021:403, para 170.

² High Level Roundtable on the Chemicals Strategy for Sustainability, Report of 25 November 2021 on "Enforcement and compliance of chemicals legislation".

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large, and investors in particular, to exercise their due diligence. REACH must allow – and oblige – the collection and publication of these pieces of information:

- Name of the parent companies in addition to the name of the registrant;
- Name of the companies (and of the parent companies) behind only representatives;
- Narrow tonnage bands for the volumes placed on the market;
- Exposure scenarios;
- Name of the companies covered by a REACH authorisation, the precise volume of SVHC produced/used as well as the quantities of emissions concerned;
- Add to Article 33 the level of granularity needed to make compulsory the notification of all the information whose notification is currently indicated as voluntary by ECHA in the SCIP database guidance.

The public must have a role in enforcing REACH

- Bringing new studies to the attention of ECHA: create a formal and efficient mechanism for third parties to feed to ECHA the hundreds of new studies that are published every month on chemicals. Currently, an assessment and regulatory conclusion based on old data is not automatically updated in light of the newest findings. In other words, the present system is static, not dynamic. This needs to be rectified.
- Bringing non-compliance to the attention of enforcement authorities: members of the public must have access to an appropriate legal procedure to submit <u>substantiated concerns of non-compliance</u> to their national competent authority, triggering the obligation to assess such concerns and take the necessary operational steps to detect breaches and prevent further non-compliance. The High-Level Roundtable on the CSS similarly recommended to set up a whistle blowing mechanism allowing "any societal actor" to report non-compliant substances and products (Recommendation 9).

Similar provisions already exist in EU legislation (e,g. in the EUTR, or in the current proposal for a Regulation on deforestation-free products), empowering members of the public to submit well-founded claims based on objective information regarding non-compliance which may require the intervention of the relevant competent authorities, and obliging competent authorities to provide a reasoned response. Another example is the Consumer Protection Cooperation Regulation (2017/2394) which requires Member States to establish an "external alert" mechanism allowing consumer organisations to alert their competent authorities of a suspected infringement of their protected consumer interests.

We see no reason that would justify the lack of similar provisions from REACH. Such a system could also be opened to competitors – an approach already employed with success in the context of EU competition law and endorsed by the High-Level Roundtable on the CSS.

• Access to justice: the European Green Deal Communication calls on the Commission and Member States to "ensure that policies and legislation are enforced and delivered effectively". This requires increasing public access to justice rights in respect of REACH obligations.



In October 2020 the Commission published its Communication on Improving Access to Justice in Environmental Matters in the EU and its Member States³ with the aim of ensuring the success of the European Green Deal by providing access to justice to individuals and NGOs as a means of enforcing EU environmental law. Significantly, the Commission acknowledged that "individuals and NGOs play a crucial role in identifying potential breaches of EU law by submitting complaints to administrations or taking cases to court" (paragraph 9).

In this context, the Commission committed itself to including access to justice provisions in EU legislative proposals for new or revised EU law concerning environmental matters (paragraph 33) and urged the European Parliament and the Council to support such proposals.

The REACH Regulation plays a significant role in the Union's pursuit of environmental protection. As such, the Commission must deliver on its commitment to include access to justice provisions in the proposal for its revision. One way of doing this would be to ensure that the public can access judicial proceedings in relation to a competent authority's response to a substantiated concern about non-compliance with REACH.

Ignoring the law does not pay – Make non-compliance a risk

Violating the law should never bring more benefits than risks. The sanctions for violations must be genuinely dissuasive and applied in a consistent manner. But the reports published on this topic so far by the Commission show that the Member States do not have a strict enough approach. REACH reform must solve this issue by aligning with the best practices in EU law.

✓ Sanctions – harmonise and strengthen

The obligations of REACH apply directly to companies across the EU and to products imported, and if the Member States applied sanctions of the same intensity and with the same regularity, that would ensure a fair level playing field. But violating REACH does not cost the same everywhere because sanctions are not harmonised. In fact, "too many incentives exist for non-compliance".⁴ REACH reform needs to do this, and do it well by importing the best sanction systems developed recently in EU law.

This involves specifying:

(i) the criteria which must be taken into account by national authorities when applying sanctions (e.g., the nature, gravity and duration of the infringement; the level of the impact generated by the non-compliance on the environment and human health);

(ii) a list of specific breaches which attract mandatory and automatic sanctions in all Member States;

(iii) an obligation to suspend the right to use or manufacture the substance concerned (under a REACH authorisation or REACH restriction's transition period or derogation) in case of a breach of the conditions set that impacts health or the environment.

³ Brussels, 14.10.2020, COM (2020) 643 final.

⁴ High Level Roundtable report on enforcement and compliance, see Recommendation 3.



(iv) certain ranges of fines and calculation methods, including by providing a percentage of a company's turnover which can be applied at the maximum level of the fine, high enough to be an effective deterrent.

Similar provisions already exist in other pieces of EU legislation, such as in Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR); Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market (the UCPD, as amended by Directive (EU) 2019/2161), and more recently the IED proposal. We see no reason justifying the lack of such provisions from REACH reform, in particular an indication of the annual turnover which can be applied at the maximum level of the fine.

The IED proposal for example requires:

Article 79

2. The penalties referred to in paragraph 1 shall include fines proportionate to the turnover of the legal person or to the income of the natural person having committed the infringement. The level of the fines shall be calculated in such a way as to make sure that they effectively deprive the person responsible for the violation of the economic benefits derived from that violation. The level of the fines shall be gradually increased for repeated infringements. In the case of a violation committed by a legal person, the maximum amount of such fines shall be at least 8 % of the operator's annual turnover in the Member State concerned.

Member States shall ensure that the penalties referred to in paragraph 1 give due regard to the following, as applicable:

(a)the nature, gravity, and extent of the violation;

(b) the intentional or negligent character of the violation;

(c) the population or the environment affected by the violation, bearing in mind the impact of the infringement on the objective of achieving a high level of protection of human health and the environment.'.

Transparency – another incentive to comply

REACH reform should add to the sanctions mentioned above other incentives for compliance. There is for example a role to play for "Name & Shine" as well as "Name & Shame". As in other areas, for example competition law, the names of companies in violation of REACH should be made public. The report by the High-Level Roundtable (previously mentioned) clearly shows support to the idea of identifying and publicising transgressors, including by "sharing the details of non-compliant enterprises, products and chemicals with consumer organisations, who in turn could assist in alerting consumers via their communication channels". This is part of their first recommendation to improve compliance with REACH.

✓ Compensation

REACH risk management measures (bans or conditions of use) are mandatory because they are indispensable to protect people's health and/or the environment. If they are respected then they ensure respect for the human right to a healthy environment (as embodied in Articles 35, 37, and 38 of the Charter of Fundamental Rights). However, it is common knowledge that this right is often breached as a result of non-compliance with chemical law, particularly when the most hazardous substances are involved, such as carcinogenics, mutagenics, reprotoxicants, endocrine disruptors or persistent, bioaccumulative and toxic chemicals.

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The human right to a healthy environment includes the right to have access to an effective compensation system (in accordance with Article 47 of the Charter) in case of harm. But national laws create excessive barriers to the fulfilment of this right because the causal link will be very difficult to prove in court. Therefore, changes must happen to guarantee that where damage to human health occurs as a result of a violation of REACH risk management measures, the individuals affected have the right to claim compensation and Member States' national procedures ensure the effectiveness of this right.

Damage claims moreover serve as an additional enforcement mechanism because companies will have to factor in possible compensation claims if they breach the terms of an authorisation or restriction under REACH.

The revision of REACH should therefore include provisions regarding the right to request and receive compensation for damages, in order to harmonise remedies at EU level. In this context, REACH should include the following aspects:

- Clarify that any person who has suffered material or non-material damage as a result of a violation of a REACH risk management measure shall have the right to request and receive compensation.

- Require companies to have insurance to cover their third-party liability under REACH and thereby ensure that the victims are justly compensated for potential damages (see for example the mandatory liability insurance regime set under the Paris Convention on Third Party Liability in the Field of Nuclear Energy).

- Facilitate victims' claims in line with the precautionary principle and the principle of prevention. The burden and/or the standard of proof required for the establishment of the causal link should not render the exercise of the right to damages practically impossible or excessively difficult. When an individual can provide prima facie proof that they suffered from health impacts from a REACH violation or could have suffered from such impacts, there should be a rebuttable presumption that they suffered harm as a result of the infringement. For example, a person should be able to request the compensation for damages on the basis of a water, soil, air, dust or product test result, delivered by an accredited specialized laboratory, which show serious exceedance of the limits imposed by REACH authorisation or restriction, provided this can be reasonably linked to any damage suffered by the person. This borrows from best practices in other areas of EU law (see, e.g., Article 8 of Directive 2000/43 and Article 19 of Directive 2006/54).

- This rebuttable presumption should prevail unless the duty holder can credibly demonstrate to the satisfaction of the court that the violation of the REACH risk management measure had no material contribution to causing the actual harm.

- A clear and reasonable limitation period should be established so that victims have sufficient time to bring an action. Victims should have at least 5 years to bring damage claims, starting from the moment when they had the possibility to discover that they suffered harm from a breach of the REACH Regulation.

- Non-governmental organisations promoting the protection of human health or the environment must be allowed to represent the individuals affected and bring collective actions for compensation, to give the most vulnerable a chance to obtain compensation. This also borrows from best practice in other areas of EU law (see, e.g., Article 7 of Directive 2000/43 and Article 17 of Directive 2006/54).



Such a right was recently included in the Commission's proposal to revise the IED and the same considerations should apply to violations of REACH.

Examples from IED

'Article 79a - Compensation

1. Member States shall ensure that, where damage to human health has occurred as a result of a violation of national measures that were adopted pursuant to this Directive, the individuals affected have the right to claim and obtain compensation for that damage from the relevant natural or legal persons and, where appropriate, from the relevant competent authorities responsible for the violation.

2. Member States shall ensure that, as part of the public concerned, non-governmental organisations promoting the protection of human health or the environment and meeting any requirements under national law are allowed to represent the individuals affected and bring collective actions for compensation. Member States shall ensure that a claim for a violation leading to a damage cannot be pursued twice, by the individuals affected and by the non-governmental organisations referred to in this paragraph.

3. Member States shall ensure that national rules and procedures relating to claims for compensation are designed and applied in such a way that they do not render impossible or excessively difficult the exercise of the right to compensation for damage caused by a violation pursuant to paragraph 1.

4. Where there is a claim for compensation in accordance with paragraph 1, supported by evidence from which a causality link may be presumed between the damage and the violation, Member States shall ensure that the onus is on the person responsible for the violation to prove that the violation did not cause or contribute to the damage.

5. Member States shall ensure that the limitation periods for bringing actions for compensation referred to in paragraph 1 are not shorter than 5 years. Such periods shall not begin to run before the violation has ceased and the person claiming the compensation knows or can reasonably be expected to know that he or she suffered damage from a violation pursuant to paragraph 1.'.

✓ Collective redress

Directive (EU) 2020/1828 on representative actions for the protection of the collective interests of consumers entered into force on 24 December 2020. Member States shall adopt and publish the relevant implementing measures by 25 December 2022. The measures shall apply from 25 June 2023.

The Directive gives certain "qualified entities" the possibility to bring injunctive and redress cases to protect the interests of consumers. It applies when a) there is infringement of a specific Directive/Regulation listed in the Annex; b) by a trader (broadly defined, including both publicly and privately owned entities); and c) there is harm or may be harm to the interests of a group of consumers.

The Annex includes several pieces of EU chemicals legislation but unfortunately REACH is missing form that list. This exclusion does not make sense. REACH risk management measures target substances on their own, in mixtures or in products available to consumers. REACH also includes provisions that aim at delivering information to the consumer (Article 33.2). A breach of safety or information obligation REACH reform must therefore address this important gap in the system of EU remedies available to consumers.



Ease of monitoring – analytical reference standard available upon request

 Obligation to provide chemical standards – give authorities and researchers the tools they need

Pure chemical standards are often necessary, especially for eco-monitoring. A <u>recent research on PFAS</u> <u>soil pollution published in Science</u> and <u>its legal counterpart</u> highlighted this need. The <u>recent strategy by</u> <u>Solvay</u> to block access to chemical standards via patent claims to prevent scrutiny showed the necessity of including in REACH an obligation on manufacturers or importers to provide access to these standards upon request. Requiring operators to "provide appropriate reference standards to enforcement authorities and to publish reference analytical methods for measurement of their registered substances" is a key recommendation from the High-Level Roundtable on the CSS (see Recommendation 5).

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