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March 2023

Demand #5 for REACH reform

Give bite to REACH: sanctions and control

The EU institutions and States spend considerable resources adopting protective chemical norms. If those norms are complied with, then harm is prevented and the efforts are fairly shared amongst chemical operators.

But today, non-compliance with REACH obligations is very high, because both controls and sanctions are insufficient and they are not harmonised.

Therefore, REACH reform needs to tighten the screw, by creating a harmonised and strengthened system of controls and sanctions.

Why is it needed? Non-compliance is sky-high

Compliance with Registration Obligations (Title II) - At the last count, nearly all (93%) dossiers submitted by industry and checked by ECHA lacked vital hazard and exposure data needed to assess the potential risks of cancer or other serious impacts, a high rate of illegality, echoing previous years.

Compliance with Supply Chain Information Obligations Information (Title VI) – A major issue is the transfer of information deficits from the chemical safety reports, in particular hazard identification and exposure scenarios, into the extended safety data sheets communicated down the supply chain. This in turn significantly affects what risk control measures the employers implement or do not implement. Similarly, the incorrect classification of mixtures leads to risks not being identified

Compliance with Downstream Users Obligations (Title V) - A Forum report finds that two thirds of downstream users violate some of their obligations under REACH, including by failing sufficiently to provide information on safe use to their own customers or to comply with risk management measures.

Compliance with Restriction Obligations (Title VIII) – 18% of products checked in 2018 did not comply with inspected REACH restrictions, which is a high rate of non-compliance considering that restrictions cover those uses of chemicals with the highest risks for health and the environment. Non-compliance is

especially problematic for substances, mixtures and articles sold online (78 % of the products checked for restrictions did not comply according to latest ECHA report, 2021).

Compliance with Authorisation Obligations (Title VII) – Infringements can range from the absence of authorisation to the failure to comply with the conditions attached to the authorisation. In its latest report from February 2023, the Forum reports that 40% of inspected companies fail to comply with their duties under the authorisation regime, which is the highest non-compliance rate observed in relation to provisions of EU chemicals legislation.[1]

This may in fact only partially capture the reality of non-compliance with REACH. As pointed out by ECHA in its report on the operation of REACH from 2021, the absence of data on an annual basis hampers the understanding of what enforcement is taking place in the EU and where harmonisation efforts should take place.

The current system incentivises non-compliance

As of today, REACH asks Member States to determine penalties applicable for REACH infringements that "shall be effective, proportionate and dissuasive" (Art. 126), without any further clarification of what that means. According to Advocate General Tanchev, Art. 126, read in the light of Art. 1(1), recitals 1 and 3 of REACH and Art. 37 of the Charter of Fundamental Rights of the EU – still obliges Member States, notwithstanding their discretion, to deploy sanctions 'which reflect the seriousness of the failure to adhere to it'. Similar conclusions were reached by the Court in other areas of EU environmental law.[2]

Generally, sanctions in the form of environmental damages are extremely low – in France for example, 70% of environmental law breaches are sanctioned with low administrative fines (in comparison, only 30% of other legal offences are sanctioned with low fines).

Some countries have set sanctions at a level that does not effectively dissuade companies from breaching REACH (for example in Slovenia, Czech Republic, Romania or Austria). This is especially true when it comes to the sanction for breaches of authorisation and restriction conditions. The Forum report on the state of compliance with REACH authorisation states that the most frequent enforcement action to sanction cases of non-compliance was "written advice".

A 2020 Milieu report confirms that by far, most of the penalties imposed on operators take the shape of insufficiently high fines. The higher the tonnage (>1000t produced or imported/y), the lower the level of fine incurred (Milieu, 2010).

The current system leads to unequal treatment in different jurisdictions

The level of sanctions and the methods of enforcement of REACH varies considerably from one country to another, which creates huge disparities across the EU and, therefore, unequal treatment, leading to an uneven 'playing field'.

[1] ECHA Forum, REF-9 project report on enforcement of compliance with REACH authorisation obligations (February 2023).
[2] In Case C-752/18 DUH v Freistaat Bayern, the CJEU stated that Member States need to provide effective and dissuasive sanctions (including for example time based financial penalties) for breaches of air quality obligations. This case is a striking example of inexistent enforcement mechanisms for environmental laws in Germany. The Court stressed that the provision of effective sanctions is linked to the need for an effective protection of fundamental rights.

As explained by the Milieu Report (2010), some countries (e.g., France and Germany) put a strong emphasis on administrative sanctions, while others (Denmark, Finland, Sweden, Poland) address most of the offences, particularly the most significant ones, under criminal law.[3] Some countries provide for complementary penalties such as the suspension of a business licence (e.g., in Luxembourg, Czeck Republic, Portugal), withdrawal of a permit (in Portugal, the Netherlands, Belgium) or seizure of assets (e.g., in Slovenia). Maximum fines imposable are high in some cases (up to 55 000 000Eur in Belgium), but very low in others (below 200 000Eur) – demonstrating a significant lack of consistency. There is even a lack of agreement on what REACH provisions are enforceable or not under national law. As a result, in some countries, the sanctions for violations of certain REACH provisions are not provided for in law. This situation is unacceptable from the point of view of protecting health and the environment, but also from the point of view of the single Market, as it creates unfair advantages for those companies in countries with weaker systems.

Violating REACH cannot be less costly than violating other EU laws

Competition law creates extremely dissuasive sanctions - Council Regulation (EC) 1/2003 on the implementation of the rules on competition laid down in Art. 101 and 102 TFEU, asks for administrative fines for certain infringements of "up to 10% of its total turnover in the preceding business year".

Dissuasive sanctions are spreading in other sectors of EU law - Dissuasive and harmonised sanctions are now integrated in many pieces of EU legislation, such as:

- 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) requires supervisory authorities to impose, for certain violations, administrative fines of 'up to 20 000 000 EUR, or in the case of an undertaking, up to 4 % of the total worldwide annual turnover of the preceding financial year', or penalties with an 'equivalent effect' (Art. 83). That comes in addition to the corrective powers attributed to supervisory authorities under Art. 58(2) and other penalties (Art. 84);

- Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market (the UCPD, as amended by Directive (EU) 2019/2161) similarly requires the imposition of fines of 'at least 4 % of the trader's annual turnover in the Member State or Member States concerned' (Art. 13);

- Regulation (EU) 2018/858 on the approval and market surveillance of motor vehicles contains detailed provisions on the type of infringements and applicable sanctions Member States should provide for (Art. 84). Art. 85 also introduces a self-standing power of the Commission to impose financial sanctions on operators, should Member States fail to do so;

- And more recently the proposal for the Ambient Air Quality Directives recast (Art. 29), or the Industrial Emissions Directive reform proposal[4] which requires:

Art. 79

[3] Criminal sanctions and administrative sanctions should both coexist as their objective, nature and requirements are very different, as confirmed by Recital 3 of the Environmental Crime Directive.

[4] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste

"*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."

The interests protected by REACH are by no means less important than the ones protected by the laws listed above. It also needs to benefit from the protection of harmonised and high sanctions.

Criminal sanctions only for most 'serious breaches' are not enough – The Commission's proposal for a revised Environmental Crime Directive broadens the current scope by covering new offence categories, such as 'serious breaches of EU chemicals legislation causing substantial damage to the environment or human health'. This is a good step, but it is not sufficient to tackle the diversity – in type and degree – of REACH violations. In addition, negotiations are ongoing and might bring changes to the original proposal. Even if the proposal is maintained, REACH will need to specify what breaches should qualify as 'serious'. If not, specific provisions on sanctions in the REACH text itself must fill in that gap.

What should it look like?

A better approach to the detection of non-compliance

Harmonisation of controls

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 to controls, for example through criteria and standards against which the effectiveness of Member States' control systems can be assessed.

In order to ensure that the criteria and standards adopted are indeed implemented, we support the creation of **a comprehensive EU audit system**, following the example of the fisheries control framework under Regulation (EC) No 1224/2009 (Title X).

The objective of such an audit system is to ensure that enforcement happens, and that it happens effectively. It would identify the structural deficiencies of any systems but also any recurring cases of non-compliance, in order to achieve fully effective implementation of EU law across the whole EU. As guardian of the Treaties, the Commission is entitled to, and should be the only body responsible for undertaking audits under REACH – both ad-hoc 'reactive' audits, based on a specific concern that has come to its attention, and more general or 'proactive' ones, with a view to detect systemic issues of enforcement or

non-compliance with REACH obligations. ECHA could support the work of the Commission. Inspection missions could be employed. Audits should be carried out by the Commission in all Member States, so that a level playing field is ensured. Audits must be flexible (i.e., responsible to emerging concerns) and adversarial. For example, Member States must be able to contribute to any audit report. The fisheries audit system specifies the setting of action plans, as a follow up to audit. The action plan is adopted collaboratively, by both Member States and the Commission. It is an opportunity for national public authorities to precisely identify and rectify enforcement issues by setting a direction of work in the context of set deadlines. Any failure to pursue the action plan can then lead to infringement procedures. This system could well be reproduced under REACH, as also envisaged by the IA report submitted to the RSB (in particular option #26).

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. But that Regulation covers only parts of REACH at the moment (limited to products available on the market). The revised REACH should have its own market surveillance provisions. Art.s 14, 14a, and 19 of the deforestation regulation proposal could give some inspiration.

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).

Systematically include obligation to monitor and report emissions, and to ensure traceability**,** in authorisation and restriction decisions.

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

Pure chemical standards are often necessary, especially for environmental monitoring. A recent research on PFAS soil pollution published in Science and its legal counterpart highlighted this need. The recent strategy employed by Solvay, to block access to chemical standards via patent claims to prevent scrutiny, shows 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).

Enlist third parties to support public authorities

The IA submitted to the RSB considers strengthening the role of consumers and civil society organisations in order to reinforce the enforcement of REACH in line with environmental fairness (p.29).

Several options could contribute to that objective:

Registration – Create a formal and efficient mechanism for third parties to flag missing information, including to feed to ECHA the hundreds of new studies that are published every month on chemicals (see our Demand #6 on the Right to trigger action from public authorities). Currently, an assessment – and regulatory conclusion – based on old data is not automatically updated in light of new findings. In other

words, the present system is static, not dynamic. This needs to be rectified. To effectively create a "hive scrutiny", REACH 2 must require the publication of key information subjected to registration (see our Demand #2 on strengthening 'No data, no market').

Obligation to communicate to customers and consumers – create a mechanism similar to the one explained above (see our Demand #6 on the Right to require action from non-compliant operators).

Obligation to respect authorisation and restriction decisions – create the right to submit issues of substantiated concern (see our Demand #6 on the Right to require action from non-compliant operators & Right to trigger action from public authorities).

Make the efforts visible

Obligation for ECHA and the competent authorities to publish an enforcement report annually (see example, from Art. 8 of Regulation 2018/858).

Sanctions

Sanctions for violation of REACH registration obligations

Grant ECHA the power to make 'no data, no market' a reality

The CSS promised to give to ECHA the power to revoke the registration number of companies, effectively excluding them from the market if they have not provided. This dissuasive and harmonised sanction might help fight the high level of non-compliance with registration obligations – including notification obligations for substances of very high concern in products (Art. 7).

Name and shame

Transparency on non-compliant operators would create a supplementary incentive needed under REACH. As in other areas, for example, competition law or the EU ETS, 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". Very recently, this concept has been incorporated in Art. 23 of the compromise text for the deforestation regulation.

Exclusion from request for authorisation and restriction derogations

An updated registration dossier must be a strict precondition for allowing operators to enjoy the benefit of being authorised, exceptionally, to continue the use of a known hazardous chemical.

Sanctions for violation of information obligation

Obligation to share information with customers and consumers

Supply chain communication to customers (SDS) or consumers (see Art. 33) is crucial to the effectiveness of REACH and one of its least effective provisions.

In case of violation of the obligation to provide information to customers, ECHA should be given the power to suspend the registration number if the non-compliance is not rectified within one month of a warning.

In case of violation of the obligation to provide information to consumers, ECHA should have the power to impose dissuasive fines against the companies concerned, and to suspend the registration number in cases of repeated offences.

In addition, ECHA should ensure transparency on non-compliance, or "**name and shame",** via public, and searchable, database of non-compliant companies.

Obligation to notify information on use from Registry of Intention/Candidate List

In REACH 2, companies – downstream users in particular – will have new obligation to notify key information to ECHA ahead of regulatory processes (Candidate List for authorisation, Registration of Intention for restrictions). Companies that do not comply with this obligation, or have not updated their registration as required, must **be excluded from applying for an authorisation or requesting a derogation.**

Authorisation applications missing information must **be automatically rejected** (1 year grace period).

Sanction for violation of authorisation and restriction decisions

Effectively suspend activities that contravene the law

Non-compliant activities can have hazardous effects (such as, for example, a company that does not respect the risk management measures imposed under a REACH authorisation). Therefore, such companies must not be allowed to continue operating until the non-compliance has ended. Competent authorities must have the competence and the obligation to impose a suspension if non-compliance is recurrent, or when the negative effects of the non-compliance on the environment and/or human health are foreseeable.

Making sanctions dissuasive, all over the EU

The obligations of REACH apply directly to companies across the EU and to products imported. However, only if the Member States apply sanctions of the same intensity and with the same regularity, will that ensure a fair level playing field. Currently, violating REACH does not cost the same everywhere, because sanctions are not harmonised. In fact, "too many incentives exist for non-compliance".[5] REACH reform needs to harmonise sanctions and enforcement, and harmonise them well, by importing the most effective sanction systems developed recently in EU law.

<u>This involves specifying:</u>

i. **the criteria which must be taken into account by national authorities when applying sanctions** (in particular: the nature, gravity and duration of the infringement; the violator's compliance record; the level of the impact generated by the non-compliance on the environment and human health, including the irreversibility of the damages; the intentional character; actions taken to mitigate the damage suffered; direct or indirect financial benefits gained or losses avoided from the violation; aggravating or mitigating factors; and whether or not the infringer promptly reported the non-compliance);

ii. **a list of breaches (specifying the degree of seriousness)** which **must** attract mandatory and automatic sanctions in all Member States;

[5] High Level Roundtable report on enforcement and compliance, see Recommendation 3.

iii. **the type of sanctions** (punitive and remedial) which may be enforced, with reference to the Environmental Crime Directive for the most serious infringements. For financial sanctions, REACH should provide certain ranges of fines (specifying the minimum fine) and calculation methods, including by providing a percentage of a company's worldwide turnover, which can be applied at least at the maximum level of the fine, high enough to be an effective deterrent – at least 8% of annual global turnover for breaches of authorisation and restriction decisions.

iv. **the obligation to set up a national register of grave infringements,** as well as an EU registry. That would make it possible to keep track and analyse the effectiveness of the enforcement response. National registers of legal breaches are known to EU law, e.g., under the control of fisheries Regulation 1224/2009 (Art. 93).[6] Ideally, both national and EU registers should be publicly available to ensure transparency and incentivise compliance.

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[6] Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations