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Catch them ‘cause you can

How lenient enforcement of REACH authorisations lets companies get away scot-free

Authors

Hélène DUGUY, Julian SCHENTEN, Ilze TRALMAKA, Sebastian BECHTEL

Internal Review

Adam WEISS, Tatiana LUJAN, Anne FRIEL

CLIENTEARTH.ORG

ClientEarth

Executive Summary

The European Chemicals Regulation REACH seeks to ensure a high level of protection of human health and the environment. This includes phasing-out ‘substances of very high concern’ (SVHCs). SVHCs can, for example, cause cancer, affect the endocrine system or are otherwise toxic and do not degrade in the environment. The REACH Authorisation regime requires industry to refrain from using these chemicals – unless they are granted authorisation. While companies are permitted to continue using these chemicals under specific protective conditions, they are ultimately expected to transition away from these harmful substances.

A 2023 report from the European Chemicals Agency (ECHA) reveals that 40% of companies across the EU do not meet their obligations under REACH Authorisation. Given the significant risks these substances pose, the high non-compliance rate uncovered by ECHA is alarming. Even more concerning is the lenient enforcement response to such widespread non-compliance. Additionally, beyond the ECHA report, there is a troubling lack of publicly available information regarding the enforcement of chemicals regulations, including the Authorisation regime.

In light of these findings, ClientEarth initiated an investigation to understand and expose the factors contributing to the low levels of enforcement of REACH authorisations, focusing on three case studies (France, Germany, and Spain) and the division of responsibilities between Member States, the European Commission, and the Enforcement Forum in ECHA.

The **Member States** are tasked with setting up effective and deterrent enforcement frameworks. Imposing “*written advice*” or formal notice (e.g. in France, for the most serious cases of non-compliance) as the harshest sanction obviously will not have strong dissuasive effects.

Moreover, ClientEarth made access-to-documents requests, revealing that national REACH competent authorities in federal systems have no oversight of enforcement which is delegated to the regional level. Since there is no monitoring or evaluation of enforcement on the ground, these States cannot demonstrate they have created an effective framework for enforcement at the national level. These shortcomings in the implementation of binding EU requirements provide grounds for the Commission to launch infringement procedures.

The **Commission** is in charge of monitoring and reviewing authorisations; it may also withdraw an authorisation if the circumstances under which it has been granted have changed.

Withdrawal, certainly in severe cases of non-compliance, is a legally binding obligation on the Commission rather than a policy option. This legal conclusion is based on taking into account:

- the high stakes in terms of risks to health and environment that violations can cause,
- the need to ensure a level playing field of enforcement, especially as Member States may face legal constraints if they seek to withdraw an authorisation themselves, and finally
- the Commission’s ultimate responsibility, as guardian of the Treaties, to ensure proper implementation of REACH.

Aside from a superficial report the Commission receives every five years from the Member States, ClientEarth’s access-to-documents request to the Commission confirmed that in practice the Commission holds little information, and therefore knows very little, about the day-to-day state of enforcement. That is why the Commission does not appear to have in place procedures to identify in a

timely manner violations detected by Member States. The Commission confirmed that it has never withdrawn an authorisation due to non-compliance.

The **Forum** is meant to be the EU's central intelligence when it comes to enforcing REACH, notably to identify related challenges and help mitigate them. The reply to ClientEarth's access-to-documents request suggests that apart from discussions of the EU-wide project that led to the 2023 report mentioned above, no exchanges take place among members about violations of the Authorisation regime.

A failure of accountability is hindering the effective enforcement of the REACH Authorisation regime. These are harmful conditions liable to give rise to a toxic blame game. The worst effects are on the EU economy, as companies build breaking the law into their business model: if a company can only turn a profit by breaching REACH authorisations, it is destined to fail, with serious consequences for consumers, employees, and the wider economy.

In addition, ECHA and the Member States studied are withholding information on enforcement. The authorities argue at great length to keep the identity of offending companies secret. Meanwhile the EU courts' jurisprudence demonstrates that non-compliance with the law is not a protected business interest. Rather, enforcement data are subject to the principle of the widest possible access to documents and that any exceptions applied must be interpreted strictly.

In response to ClientEarth's access-to-documents requests, Germany and Spain refrained from providing any information apart from what is already in the public domain.

It is of particular concern that Germany informed ECHA of its intention to reconsider its participation in the Enforcement Forum should the Agency grant ClientEarth access to the documents requested.

The lack of transparent enforcement activities and outcomes removes a key incentive for companies to comply, an incentive that depends on exposing to public scrutiny violations of the Authorisation regime for the most dangerous chemicals. As a result, **civil society is also prevented from fulfilling its critical role:** drawing attention to shortcomings in compliance with and enforcement of REACH, and thus strengthening enforcement and improving lawmaking when the time comes for reform.

This report underscores the significant risks of allowing the most harmful chemicals to remain on the market, on the basis that companies will implement site-specific risk management measures. Given the widespread non-compliance and the lack of robust enforcement, **reliance on emission controls and operational conditions can only complement but never replace strict regulation**.

In light of the anticipated revision of REACH which, in particular, is meant to involve changes to the Authorisation regime, legislative reform needs to be based on a solid understanding of the implementation of law as it stands – which at the moment is simply not available.

This report's recommendations include the introduction of a clear accountability framework between the authorities at EU and national level, ensuring effective enforcement: in France for example one could see that companies who received a formal notice, i.e. the strictest form of reminder to comply, implemented the necessary steps to comply with the authorisation concerned, indicating that **the strongest sanctions provide the biggest incentive to comply**.

The report further suggests amendments to REACH, addressing the shortcomings in enforcement. The report proposes additional measures to enhance the transparency of enforcement results.

Contents

1 Introduction

1.1 Aims of the report

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

Yet **non-compliance with the main EU chemicals 'REACH' Regulation is widespread**, abetted by inadequate controls and sanctions. This problem spans many obligations the regulation imposes, from companies failing to properly register their chemicals to a lack of compliance with chemical bans.

Of particular concern is the Authorisation regime, which addresses the most hazardous chemicals in the EU - the ones that should simply disappear from the market. The patterns of non-compliance in this context are especially alarming given the potential risks involved. Moreover, as the Authorisation system almost exclusively applies to uses within the EU,[1] the high rates of non-compliance are for the most part attributable to EU companies, i.e. not the alleged third-country 'rogues' who usually take the blame when the EU discusses non-compliance with chemical laws.[2]

Enforcement actions to address and reverse these issues have been notably inadequate.

In 2023, the ECHA Forum, in charge of coordinating enforcement actions across the EU, in the so-called REF-9 report observed that 40% of companies inspected fail to comply with their Authorisation duties.[3] This was the highest non-compliance rate ever observed.[4] Infringements range from the use of a chemical without authorisation to the failure to comply with the conditions attached to the authorisation. Worryingly, enforcement responses have been largely insufficient, according to the sparse information in the report. 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 produced on an annual basis (or even more frequently) hampers the understanding of what enforcement is taking place in the EU and what harmonisation efforts should be focused on.[5] Missing enforcement data suggests a lack of understanding about how industry implements Authorisation. In other words, the authorities are missing information that is necessary to devising sound legislative reform.

Considering this state of play, our report seeks to illuminate the shortcomings in the enforcement of the Authorisation framework, which, due to the significant risks associated with non-compliance, should be a high priority for national and EU authorities. The report explores the roles and responsibilities of both EU and national authorities in addressing non-compliance. It also aims to provide a practical examination of enforcement practices in selected countries, focusing on transparency and access to information related to enforcement of chemical laws.

[1] Besides the import of substances subject to authorisation, which is a rather rare case.
[2] CEFIC: "*More than 90% of all chemicals in consumer products non-compliant with REACH come from outside of the EU*".
[3] ECHA (2023), REACH Enforcement Project (REF)-9 report on enforcement of compliance with REACH authorisation obligations.
[4] ECHA (2023), REACH Enforcement Project (REF)-9 report.
[5] ECHA (2021), Report on the operation of REACH and CLP 2021.

1.2 Why we need meaningful enforcement

The mere existence of laws is rarely sufficient to ensure their success. **Enforcement mechanisms are considered essential for ensuring effective implementation of legal standards.** Enforcement involves ensuring that individuals and private and public organisations comply with the law and, when they do not, suffer sanctions that are sufficiently dissuasive to incentivise future adherence.

In areas of shared competence between the EU and its Member States – such as chemicals or environmental regulation – enforcement has historically been the responsibility of national authorities. Nevertheless, as guardian of the Treaties, the European Commission also holds a key responsibility: monitoring national enforcement and taking action where enforcement is inadequate or missing. Low levels of enforcement can be observed across Member States.[6]

Several reasons might explain this situation – from a lack of institutional capacity to conduct and follow up on inspections, to some authorities' desire to promote a culture of collaboration with industrial actors. However **insufficient action against non-compliance encourages further violations and undermines the effectiveness of important regulatory frameworks such as REACH**. This not only increases risks to people and the environment, but also erodes public trust in authorities. Additionally, **the financial cost of non-compliance is substantial:** fully implementing EU environmental laws could save approximately €55 billion annually in health and environmental costs.[7] It is thus no surprise that enhanced enforcement of chemical regulations is a key priority for the Commissioners-designate responsible for chemicals policy.[8]

1.3 Why we need enforcement data and transparency

Transparent enforcement is crucial for several reasons.

Firstly, transparency ensures accountability on all levels: private, national and EU. Although the argument is often put forward that enforcement relies on negotiation and cooperation, this does not stand up to scrutiny. To protect the rule of law, non-compliance with environmental law must be met with a clear and automatic no-tolerance approach. Unless EU law is implemented and complied with, the wider public receives very little benefit from it or from the institutions in charge of adopting and enforcing that law.

Secondly, citizens have a right to know. Article 42 of the Charter of Fundamental Rights of the European Union enshrines a fundamental right of access to documents. This right is further solidified in Article 10 of the Treaty on European Union, Article 15 of the Treaty on the Functioning of the European Union, Regulation 1049/2001 (Access to Documents Regulation),[9] Regulation 1367/2006[10] (Aarhus Regulation),

[6] OECD (2011), *Environmental Enforcement in Decentralised Governance Systems*.
[7] European Commission, Environmental Implementation review.
[8] See notably the written answers of Commissioners designate Roswall and Séjourné.
[9] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.
[10] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

and the Aarhus Convention.[11] The latter two in particular promote broad access to environmental information, which includes information on the enforcement of environmental law.[12] This right is especially significant when the information is related to the enforcement of laws adopted to protect human health and the environment from particularly harmful chemicals.

Thirdly, laws should be made based on evidence.[13] This includes any reforms or amendments to existing laws, which should only be made on the basis of comprehensive, accurate and up-to-date information on how the current law is enforced in practice. The Treaty on European Union puts participatory democracy at the core of the Union. Article 10(3) in particular requires that every citizen have the right to participate in the democratic life of the Union and that decisions be taken as openly and as closely as possible to the citizen. Citizens also have the right to have access to economic analysis and other assumptions behind environmental decision-making, including legislative action.[14]

Finally, accurate information on enforcement is crucial for non-governmental organisations, journalists, academics and other members of society to fulfil their role – that is about scrutinising the actions and decisions of national governments, EU institutions and industries, increasing accountability and contributing to better decision-making in future.

1.4 The last chance regime: SVHC Authorisation

The core objective of the REACH Regulation is to ensure a high level of protection for humans and the environment against harmful chemicals. Special attention is given to substances that pose a *very high concern* to society, for example carcinogens, chemicals toxic for reproduction and endocrine disruptors.[15] Due to their inherently dangerous properties, these chemicals are slated for phase out. That means companies that produce or use such substances must transition to safer alternatives.

To support this transition, REACH provides instruments to the Member States and the European Commission to identify chemicals as 'substances of very high concern' (SVHCs) and, in a subsequent procedure (see the box below), add them to a dedicated Annex XIV.

Some of the blacklisted chemicals that are known to be used in many industries include Chromium Trioxide, Nonylphenol and Octylphenol (and their ethoxylates), Sodium Dichromate, Potassium Dichromate, Trichloroethylene, Dichloroethane and 4,4'-Methylenedianiline (MDA).[16]

Listing a substance in Annex XIV results in a ban on all uses of it, usually taking effect after a transitional period. Exemptions or temporary authorisations may be granted. The Authorisation process[17] offers

[11] Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, 25 June 1998.
[12] Article 1(d)(iii) and (iv) of the Aarhus Regulation and Article 3(b) of the Aarhus Convention.
[13] See Better Regulation Guidelines, Chapter I, Section I "Key Concepts and Principles of 'Better Regulation".
[14] Article 1(d)(v) of the Aarhus Regulation.
[15] Recital 69, REACH : "*To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention*".
[16] See https://echa.europa.eu/authorisation-list.
[17] Detailed in Article 60, REACH.

companies a temporary opportunity to continue using the SVHC while they work on developing a safer alternative.

Given the REACH Regulation's focus on protection and the significant risks posed by SVHCs, authorising their continued use must be exceptional and subject to strict oversight once granted. Reflecting these considerations, the REACH Regulation establishes two main safeguards.

The first one is the initial procedure to grant authorisation. The legal text provides that companies may only benefit from such authorisation if they can prove: either that the risk of that SVHC is adequately controlled, when feasible,[18] or, that the benefits of continued use outweigh the risk in the absence of available alternatives (the 'socio-economic route'). The merits and credibility of each application for authorisation are assessed within ECHA by the Committees on Risk assessment (RAC) and Socio-Economic assessment (SEAC). Eventually, the European Commission in cooperation with the Member States takes a final decision, informed by ECHA's opinion. Although the regime is intended to limit temporary exemptions to only the most necessary cases, in practice, authorisations have been granted for nearly every application submitted, even when the justification was insufficient.[19] A recent Ombudsman report further sheds light on the failure by the European Commission to implement this regime properly and in a timely manner, as the principle of good administration requires.[20]

The second crucial safeguard against the risks posed by SVHCs – and the focus of this report – is the obligation to ensure that companies fully comply with their obligations once an authorisation has been granted. That obligation falls on the European Commission, as the granter of authorisations, and on the national authorities. **Strict enforcement is essential not only to maintaining tight control over companies benefiting from exemptions but also to ensure that the ultimate goal of the REACH framework — substitution — remains a priority and is actively pursued.**

Various EU reports recognised that the requirement for companies to obtain authorisation before using harmful chemicals has sped up substitution and reduced risks to people's health and the environment.[21] However, that outcome depends on everyone involved doing their job.

[18] The 'adequate control' route only applies to substances for which it is possible to derive a DNEL. That excludes non-threshold substances such as carcinogens or endocrine disruptors. In practice this route is rarely relied upon.
[19] EEB (2017), A Roadmap to Revitalise REACH.
[20] European Ombudsman (2024), Commission delays concerning decisions on dangerous chemicals is maladministration.
[21] Notably: ECHA (2021), Socio-economic impacts of REACH authorisations, Report on the operation of REACH and CLP 2021.

Box 1: The procedures for identification of SVHCs and inclusion in Annex XIV

The formal process begins with a proposal from ECHA or a Member State to identify a substance as SVHC because it meets the criteria set out by Article 57, namely because the substance fulfils the classification criteria for carcinogenicity, mutagenicity or reprotoxicity, has 'PBT' (*persistent, bioaccumulative and toxic*) properties or 'vPvB' (*very persistent and very bioaccumulative*) properties or because there is scientific evidence of an equivalent level of concern. Article 59 of REACH defines the procedure for the identification of SVHCs: the proposal is discussed among Member States and subject to public consultation where 'interested parties', including affected industries and NGOs, have the opportunity to provide input. If Member States support the proposal, the substance is added to the 'candidate list' of SVHCs to be subjected to authorisation.

Article 58 sets out the procedure for SVHCs on the candidate list to be included in Annex XIV. ECHA recommends which substances should be picked first. According to Article 58(3) "[p]riority shall normally be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes". Following that, Member States and all 'interested parties' have the possibility to comment on the recommendation. Ultimately, decisions to include an SVHC in Annex XIV are taken in the 'regulatory procedure with scrutiny', in which Member States vote on a proposal by the European Commission.

As of November 2024, the candidate list contains 241 entries, some of which cover more than one substance.[22] Out of these, 59 entries have been added to Annex XIV of REACH.[23]

1.5 Method and structure

To better understand current enforcement, while taking account of different practices at national level, we selected three Member States in a case study approach: France, Germany and Spain. In all three countries, there is a large manufacturing sector, a fact that we see as an indication that enforcement should be on a large scale. The latter is also confirmed by the REF-9 report.

The report builds on the enforcement data publicly available for these countries, e.g. covered by REF-9[24] and the reports published under Article 117(1) of REACH. In addition, ClientEarth made access-to-documents requests within those countries (at national level) as well as with the European Commission and ECHA. Background talks with experts knowledgeable about enforcement practice further inform the assessment.

Section 2 provides ClientEarth's legal interpretation of the tasks and mandates that REACH assigns to authorities, providing the yardstick for the assessments in what follows. Section 3 contains the reality check, casting light on the lack of transparency concerning enforcement activities – which severely hampered the making of this report. It also analyses the limited empirical data that are available, data which provide clear evidence for unacceptable shortcomings. Finally, Section 4 makes recommendations.

[22] See Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu).

[23] See Authorisation List - ECHA (europa.eu).

[24] The ECHA website section dedicated to the Forum provides information on all enforcement projects, including reports with project results where available such as in the case of REF-9. Apart from this, ECHA does not share additional information on actual enforcement activities.

2 Enforcement tasks for authorities

Like other environmental regulations, REACH would be ineffective without robust controls and measures in place to address companies' non-compliance with their main duties contained in the legal text.

Under REACH, enforcement rests in the hands of national authorities,[25] but "*good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission*" are needed for the broader framework to operate effectively.[26] Therefore, the responsibility for ensuring the proper functioning of the REACH system is not merely an endeavour for national authorities. It requires all authorities – including at EU level – to play their part fully.

2.1 Duties of industry

In the context of REACH Authorisation, **companies have strict obligations** under Titles VII ('Authorisation') and IV ('Information in the supply chain') of REACH. These obligations are meant to ensure a high level of protection while encouraging industry to phase out, as soon as feasible, the manufacture and use of SVHCs.[27] A summary of these obligations is set out below.[28]

[25] Article 125, REACH.
[26] Recital 120, REACH.
[27] Article 55, REACH, recalls: "*The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution*."
[28] In addition, the presence of SVHCs in articles above the threshold of 0.1 % (by weight) triggers reporting obligations in the supply chain under Article 33(1), and upon request towards the consumer under Article 33(2) REACH. There may also be a need to register SVHCs in articles subject to Article 7 REACH. All these obligations apply to SVHCs, regardless of whether they are listed in Annex XIV or not. They are therefore not in the scope of enforcement measures on REACH authorisations.

Table 1. Companies' REACH Authorisation obligations (depending on their position in the supply chain)

	Before the authorisation is granted	**After the authorisation is granted**
SVHC Manufacturer or Importer	→ Refrain from placing an SVHC on the market for an unauthorised use, and from using an SVHC covered within the scope of authorisation after the sunset date, unless the use is exempted or an authorisation for that use has been granted to their immediate downstream user.[29] → Apply for upstream authorisation covering all identified uses by downstream customers.[30]	→ As holder of the authorisation, include the authorisation number on the labels without delay after the authorisation number has been made available.[31] → Update the safety data sheet (SDS) in the light of the authorisation decision.[32] Suppliers who do not have to supply a safety data sheet must still communicate down their supply chain if the substance is subject to authorisation and, if so, the details of that authorisation.[33] → Use the SVHC in accordance with the conditions of the authorisation granted to them or to an actor further up their supply chain for this same use.[34] → Ensure that “*the exposure is reduced to as low a level as is technically and practically possible*”.[35] →Grant workers and their representatives access to the information on the authorised substance and use.[36] →Submit a review report at least 18 months before the expiry of the time-limited review period in case they want to renew the authorisation.[37]

[29] Articles 56(1)(a),56(1)(b), 56(1)(e), 56(3), 56(4), 56(5), 56(6)1, REACH.
[30] Article 62, REACH.
[31] Article 65, REACH.
[32] Article 31(9), REACH.
[33] Article 32(1)(b) and 32(3)(b), REACH.
[34] Article 56(2); and Articles 60(9)(d), 60(9)(f), REACH.
[35] Article 60(10), REACH.
[36] Article 35, REACH.
[37] Article 61, REACH.

Downstream user	→ Refrain from placing a substance on the market after the sunset date if the substance is included in Annex XIV, unless their own uses are covered by an upstream authorisation or exempted from the authorisation requirement.[38] In this case downsteam users must: - Within three months, notify ECHA of the uses, including the notifying legal entity, site address, the authorised substance and authorised use, further description of the use (voluntary), involvement in substitution activities (voluntary), yearly tonnage (voluntary) and, if applicable, the conditions imposed by the authorisation decision (e.g. monitoring).[39] - Update the chemical safety report (CSR) and SDS (exposure scenarios). → If their use of the SVHC is not covered by a valid authorisation, they must apply for authorisation themselves.[40]	→ When holder of the authorisation, they must include the authorisation number on the labels.[41] → Use the SVHC in accordance with the conditions of the authorisation granted to them or an actor further up their supply chain for this same use.[42] → Identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified, e.g. in the safety data sheet supplied to them.[43] → Pass on any new information on hazardous properties of the chemical in question or information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him for a specific use.[44] → Grant the workers and their representatives access to the information on the authorised substance and use.[45] → When holder of the authorisation, submit a review report at least 18 months before the expiry of the time-limited review period in case they want to renew the authorisation.[46]

[38] Article 56, REACH.
[39] Article 66(1), REACH.
[40] Article 62, REACH.
[41] Article 61(1), REACH.
[42] Article 56(2); and Articles 60(9)(d), 60(9)(f), REACH.
[43] Article 37(5), REACH.
[44] Article 34, REACH.
[45] Article 35, REACH.
[46] Article 61, REACH.

Through these obligations, the REACH text makes clear that receiving authorisation is no privilege, but a crucial responsibility for companies. It entrusts them with a pivotal role in implementing appropriate risk management measures while actively pursuing the substitution of these substances. This philosophy is further emphasised in the REACH recitals: "*For any substance for which authorisation has been granted, and for any other substance for which it is not possible to establish a safe level of exposure,* ***measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects"***.[47] Companies must identify "*measures to ensure adequate control […] in any Chemical Safety Report. These measures should be applied and, where appropriate, recommended to other actors down the supply chain*".[48]

This high standard of protection underscores the critical importance of robust enforcement. **The system runs on trust in companies. It will only work if there are visible consequences when that trust is betrayed**.

2.2 Duties of the European Commission

2.2.1 Granting and reviewing the authorisation

The European Commission is the central entity in the Authorisation regime. It is first and foremost the main body responsible for *"taking decisions on applications for authorisations"*.[49] It is also the authority competent to review authorisation decisions with a view to amending, withdrawing or even prolonging them in case the company were to ask for a renewal.[50] The Commission was given that pivotal role to ensure the sound functioning of the internal market.[51]

The Commission's power is nevertheless limited. Given the enormous risk of SVHCs severely compromising the high level of protection that REACH pursues, the legal text further specifies how the Commission is to exercise its responsibility. Notably, REACH allows the Commission to grant an authorisation for SVHCs "*only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable*".[52] **The Commission "*shall normally*" subject any authorisation it grants to conditions, including monitoring**[53]. Moreover, "*[w]hen granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision*".[54]

Furthermore, the authorisation decision cannot be indefinite: it must specify a time-limited review period.[55] Regardless of this period**, the Commission "*at any time*" may decide to review the**

[47] Recital 70, REACH.
[48] Recital 70, REACH.
[49] Article 60(1), REACH.
[50] Article 61(2), REACH.
[51] Recital 69, REACH.
[52] Recital 22; cf. Article 60(2)-(5), REACH.
[53] Article 60(8), REACH.
[54] Article 60(2), REACH.
[55] Articles 60(8) and 60(9)(e), REACH.

decision.[56] It may do so if the circumstances of the original authorisation have changed in terms of risks or socio- economic impact or when new information on possible substitutes becomes available.[57] Consequently, **even in the event that a company has been granted authorisation, the Commission still holds the pen as the authorisation is only "*valid until the Commission decides to amend or withdraw*" it.[58]**

By mandating the Commission to suspend the authorisation pending the review *"[i]n cases where there is a serious and immediate risk for human health or the environment*",[59] the legal text once again underlines what is at stake if SVHCs are not adequately controlled and puts the responsibility of ensuring the sound functioning of the regime on the Commission.

2.2.2 Changing circumstances

If circumstances change in terms of risks, the Commission may initiate a review of an authorisation it has already granted.[60] For example, a violation of environmental quality standards or of environmental objectives under water laws may trigger the review.[61] And so can changes regarding discharges, emissions and losses of the substance, including risks arising from diffuse or dispersive uses.

Obviously, the actions by the companies directly granted authorisations, or which benefit from an authorisation in the supply chain, have considerable impacts on the day-to-day management of the risks. The authorisation decision relies on compliance with the risk management measures considered adequate by the Risk Assessment Committee.[62] **The authorisation assumes industry will comply with any conditions imposed.**

2.2.3 Compliance monitoring

It follows that the Commission first has to establish that the conditions in Article 61 are met; it is consequently entitled to adapt or withdraw any granted authorisation due to changed circumstances. Hence, **to fulfil the responsibility assigned to it by REACH, the Commission needs to monitor those circumstances.** As violations of Authorisation provisions by industry are a key driver for changing circumstances, the monitoring need also extends to industry compliance.

REACH assigns to the Member States the task of monitoring (see section 2.3). Yet Member States are only obliged to report to the Commission about enforcement activities and results at the national level every five years. Hence, to fulfil its responsibility, the Commission cannot exclusively rely on the mechanisms explicitly defined by REACH.

[56] Article 61(2), REACH.
[57] Article 61(2), REACH.
[58] Article 61(1), REACH.
[59] Article 61(3), REACH.
[60] Pursuant to Article 61, REACH.
[61] Article 61(4), (5), REACH.
[62] Articles 62(4)(d), 60(4)(a), 64(4)(a), REACH.

2.2.4 Withdrawal as response to non-compliance

Considering that non-compliance may significantly affect the circumstances of an authorisation that has been granted, it may trigger a review process leading to the eventual withdrawal of the authorisation. However, to achieve this outcome in cases of non-compliance, the Commission is not bound to stick to the review procedure.

Being entitled to grant an authorisation under REACH, the European Commission also has authority to withdraw such an authorisation (direct withdrawal). First, the legal text explicitly mentions the Commission's power of withdrawal – in the context of the review. In addition, there is a general principle of law according to which, in the words of the General Court of the EU, "*a body which has the power to adopt a particular legal measure also has the power to abrogate or amend it by adopting an actus contrarius, unless such a power is expressly conferred upon another body*".[63] Hence, as REACH explicitly gives the Commission the power to grant an authorisation, the regulation thereby implicitly also empowers the Commission to withdraw such an authorisation. It moreover appears that the Commission as the issuer of the decision has unique authority to withdraw it. The Member States on the other hand may face legal challenges when trying to abrogate an administrative act issued by an EU authority.

To withdraw an authorisation in the context of a review, the Commission has to meet the burden of proof; it is therefore appropriate that REACH provides a framework for the process. This framework comprises a procedure, including the involvement of the authorisation holder, and criteria such as 'changed circumstances' and the principle of proportionality.[64]

REACH does not provide an explicit framework for the direct withdrawal following the detection of a non-compliance (i.e. outside the context of a review). Given the fact that non-compliance is self-evident, a distinct procedure to establish grounds for withdrawal is however not needed. As regards the assessment criteria, basic principles of administrative law such as legal certainty apply in any case. Also the principle of proportionality, which would bar the Commission from withdrawing an authorisation due to a 'minor'[65] violation, applies. In any case, companies which doubt the legality of a withdrawal decision can bring an action before the EU courts, in accordance with Article 263 of the TFEU, contesting that decision.

2.3 Duties of the Member States

While the Commission has the authority to grant, renew, and withdraw authorisations, **Member States play an equally critical role.**

[63] See judgment of 10 March 2021, *ViaSat v Commission*, T-245/17, EU:T:2021:128, paragraph 117, referring to judgments of 20 November 2002, *Lagardère and Canal+ v Commission*, T-251/00, paragraph 130; of 15 December 2016, *Spain v Commission*, T-808/14, EU:T:2016:734, paragraph 40.

[64] Article 61(2), (3) in conjunction with, REACH.

[65] For instance, a company – without bad record of non-compliance – misses out on putting the authorisation number on a label for a chemical product.

First, they significantly influence the decision-making process **by voting on whether to grant or refuse authorisation,** with the power to block an authorisation if a qualified majority is not achieved.[66] **Second, they are responsible for enforcing the Authorisation regime within their territories,** including the implementation of any authorisations granted.

The REACH text places a high bar in terms of what enforcement is expected to look like. Enforcing an authorisation means that **Member States must "*maintain a system of official controls and other activities as appropriate to the circumstances*".**[67] Monitoring and control measures must be "*effective"*, in particular "*the necessary inspections should be planned, carried out and their results should be reported*".[68] Moreover, national authorities are required to set up "*an appropriate framework*" for penalties so that they are effective, proportionate and dissuasive against possible infringements.[69] **They must in any case "*take all necessary measures*"** to ensure an authorisation's provisions are effectively implemented, **including sanctions.[70]**

In relation to penalties, Advocate General Tanchev clarified that Article 126 of REACH, read in the light of Articles 1(1), Recitals 1 and 3 of REACH and Article 37 of the Charter of Fundamental Rights of the EU obliges Member States, notwithstanding their discretion, to deploy sanctions "*which reflect the seriousness of the failure to adhere*".[71] Similar conclusions were reached by the Court in other areas of EU environmental law.[72] **The gravity of these messages matches what is at stake: when companies breach REACH authorisations, they put lives and the natural world in which the economy is embedded at risk.**

Finally, Article 117(1) of REACH mandates that Member States submit a report to the Commission every five years on the operation of REACH within their jurisdictions. This report should also cover "*enforcement as described in Article 127*", including "*the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period*". The information Member States must share is meant to support the Commission in taking timely and necessary measures to fulfil its obligations as the guardian of the Treaties.[73] **The overall functioning of REACH Authorisation is conditioned upon that reporting;** it is

[66] Pursuant to Article 133(3), REACH, referring to Article 5, Regulation 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.
[67] Article 125, REACH.
[68] Recital 121, REACH.
[69] Recital 122, REACH: "*In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance, as non-compliance can result in damage to human health and the environment*."
[70] Article 126 REACH.
[71] Opinion of Advocate General Tanchev delivered on 21 December 2016, in Case C-535/15 *Freie und Hansestadt Hamburg v Jost Pinckernelle,* paragraph 73.
[72] 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.
[73] Recital 116, REACH.

therefore crucial that the information gathered by Member States is accurate, specific and reported in time.

2.4 Duties of ECHA

REACH establishes ECHA as the 'Agency' to secure the effective management of the technical, scientific and administrative aspects of the regulation at Union level, and ensure the consistent implementation and enforcement of REACH.[74] With regard to the latter, t**he Agency comprises a 'Forum for Exchange of Information on Enforcement' ('Forum') which coordinates a network of Member State authorities responsible for enforcement of REACH**.[75]

Tasks of the Forum include coordinating the exchange of inspectors, identifying enforcement strategies and best practice in enforcement, as well as highlighting problems at Union level.[76] For example, the Forum developed and, via its members, executed the REF-9 project on the enforcement of compliance with REACH Authorisation obligations.[77] The Forum also agrees on the contents of Member State reports following Article 117(1).[78] One of its tasks has been to propose an EU wide enforcement strategy. This includes the elaboration of minimum criteria for inspections.[79]

While the Forum is chaired by a Member State representative,[80] it is governed by ECHA's Secretariat which reports to the Executive Director[81]. Hence, to coordinate the Forum effectively and fulfil its related duties, **the Agency must always be informed about the state-of-play in compliance and enforcement issues.** Figures on the resources available to the Forum are not available, but ECHA observed in 2021: "*With a view of the need to further strengthen the enforcement of REACH and CLP[82], it would be necessary to find ways to ensure that all Forum members have enough time allocated to contribute to Forum activities, and sufficient levels of support from their Member States, as required by REACH. The scarcity of Member State resources at Forum level indicates that enforcement at Member State level could benefit from better resourcing*".[83]

Besides performing managerial tasks, ECHA is the central authority responsible for evaluating if substance data submitted by industry in the context of the registration scheme comply with the REACH information requirements. The Agency does not however enforce detected non-compliance. Rather, if companies refuse to implement the evaluation results,[84] ECHA hands over these cases to Member

[74] Article 75, and Recitals 15, 95, REACH.
[75] Article 76(1)(f), REACH.
[76] Article 77(4), REACH.
[77] ECHA (2023), REACH Enforcement Project (REF)-9 report..
[78] Article 127, REACH.
[79] ECHA (2017), Strategies and minimum criteria for enforcement of Chemical Regulations.
[80] See Article 7(1) of the Forum's Rules of Procedure.
[81] Article 76(1)(g), REACH.
[82] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
[83] ECHA (2021), Report on the operation of REACH and CLP 2021, p. 60.
[84] That is final decision, sometimes after court cases, see ECHA's review of the Joint Evaluation Action Plan presented to CARACAL.

States for enforcement. In cases of (persistent) non-compliance, REACH does not provide for sanctions such as the withdrawal of the registration number (i.e. a market ban).[85]

As concerns the Authorisation regime, Article 66(2) assigns to the Agency the task of providing a register of information on SVHC uses as notified by downstream users under Article 66(1). The register collects site-specific evidence, in particular on SVHC use categories, and, where imposed by conditions under the authorisation decision, monitoring data (e.g. occupational exposure). It thereby "*allow[s for] effective monitoring and enforcement of the authorisation requirement*"[86] both at Member State level and with regard to the Commission's review activities.

In addition, ECHA states it publishes all "*public information from downstream user notifications*" on its website.[87] Given that "*confidence*" in the Agency is "*essential*" and that for "*this reason, it is vital to ensure its independence (…) as well as transparency*"[88] more dissemination appears necessary.[89]

2.5 A delicate system of shared responsibilities

The responsibility of ensuring the good implementation of the Authorisation regime is not entrusted to one entity but has been fairly split among various actors – with what appears to be a view to sharing the burden of ensuring its effectiveness.

On the one hand, **Member States** have the task of ensuring the day-to-day monitoring and enforcement of individual authorisations. They are the ones who interact with operators and they must report to the EU authorities what is taking place on the ground. Importantly they are the ones who observe non-compliance(s) and should logically suspend a non-respected authorisation decision until the non-compliance is resolved.

On the other hand, **the Commission**, as the overarching REACH authority, must ensure it is always aware of any non-compliance as this severely affects the risks linked with an authorisation decision. It is legally entitled to withdraw an authorisation in response to non-compliance, subject to basic principles of administrative law such as proportionality.

Taking into account:

- the high stakes in terms of risks to health and environment that violations can cause,
- the need to ensure a level playing field of enforcement, especially as Member States may face legal constraints when attempting to abrogate an EU administrative act, and finally

[85] In order to receive a registration number and thereby to lift the 'no data no market' barrier, registrants have to submit a data set that is "*complete*", see Article 20, REACH. Hence, as the compliance of data does not constitute a prerequisite for the assignment of that number, a non-compliance of data determined later may not be seen as basis to withdraw it. This situation is thus barely comparable with the authorisation scheme, which does constitute a pre-market approval framework, from which we derive an implicit right to withdraw such approvals if necessary (see above).
[86] Recital 82, REACH.
[87] See https://echa.europa.eu/de/du-66-notifications.
[88] Recital 95, REACH.
[89] See https://www.clientearth.org/media/r2momo10/10-years-in-time-for-echa-to-disseminate-strategic-information-to-empower-third-parties-ce-en.pdf.

- the Commission's ultimate responsibility, as guardian of the Treaties, to ensure proper implementation of REACH,

direct withdrawal, in severe cases at least, is a legally binding obligation for the Commission rather than a policy option.

Finally, **ECHA and its Forum** have a crucial coordinating role when it comes to the enforcement of Authorisation. Their key function is to serve as a 'repository' of all useful information in order to support best practices, both by national authorities and companies, and recommend follow up actions to the Commission when needed. In their role, they must always be ahead of the curve.

3 Reality check in specific countries

3.1 Overall state of REACH enforcement in the EU

Despite ambitious laws, the effectiveness of the EU regulatory order is often compromised when it comes to environmental norms by unharmonised, low and practically inefficient enforcement at national level.[90] A specific example is France, where 70% of environmental law breaches are sanctioned with low administrative fines.[91] The efforts to ensure proper REACH implementation are equally concerning.

Recent reports on the implementation of REACH revealed alarmingly high levels of non-compliance with the regulation's obligations. In 2019, several Member States reported striking figures, with non-compliance rates reaching 62% in Sweden and 72% in Ireland.[92] These rates are percentages on performed controls rather than all companies, so they only partially capture the reality of non-compliance. The latest data from the ECHA Forum on the state of enforcement of the Authorisation regime confirms a 40% rate of non-compliance with this specific regime – and this covers only a portion of all the companies using substances of very high concern that belong to the Authorisation list.[93] The highest non-compliance rates observed in this project were for duties related to downstream users, such as the obligation for suppliers to update their safety data sheets "*without delay*" once an authorisation is granted, so that the information including the implementation of safety measures is passed down the supply chain (Article 31(9) of REACH). It is evident from the report that such deficiencies endanger the entire risk-management system meant for the downstream users of the most harmful chemicals.

Despite these significant breaches, enforcement actions remain surprisingly limited, falling short of what such high levels of non-compliance would seem to warrant.

Firstly, the level of sanctions and enforcement methods set in the law varies significantly between Member States, creating substantial disparities across the EU and therefore, unequal

[90] As recognised, notably, by the Third EU Environment Action Programme in Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' Text with EEA relevance.
[91] See https://www.courdecassation.fr/files/files/Parquet%20g%C3%A9n%C3%A9ral/Rapport_PG_envir.pdf.
[92] Milieu Consulting (2020), Technical assistance to review the existing Member States reporting questionnaire under articles 117(1) of REACH and 46(2) of CLP.
[93] ECHA (2023), REACH Enforcement Project (REF)-9 report.

treatment of companies.[94] Notably, there is a lack of consensus across member states on which REACH provisions are enforceable under national law. This has resulted in some countries not having legal sanctions in place for certain REACH violations. Additionally, enforcement approaches vary widely. While some Member States, like France and Germany, focus on administrative penalties, others, such as Denmark, Finland, Poland, and Sweden, address the most significant violations under criminal law. Certain States, including Czechia, Luxembourg, and Portugal, impose complementary penalties such as business license suspensions, while Portugal and others, including Belgium and the Netherlands, may revoke permits or (as in Slovenia) seize assets. Maximum fines also differ significantly: in Belgium, penalties can reach as high as €55 million, whereas in other States, fines are often under €200,000. In Austria, Czechia, and Romania, penalties are so low that they fail to create a meaningful deterrent, undermining efforts to encourage compliance with the regulation.

The insufficient resources and capacities allocated to the implementation of REACH are also an important hurdle to proper enforcement.[95] In the Netherlands for example, 20-25 inspectors are (partly) involved in REACH enforcement. Austria, Denmark, Luxembourg and Slovakia, each allocate fewer than 20 members of staff. **In most Member States, inspectors have broader duties than chemicals regulation and few of them have attended a REACH-specific training**.[96]

Finally, **the penalties that are applied in practice are often too lenient** to enforce compliance effectively. Specifically concerning Authorisation, the main information source available today, the ECHA Forum REF-9 report, highlighted in 2023 that **the most common enforcement action that has been imposed on non-compliant operators has been "*written advice*"**.[97] A 2020 Milieu report further supports this assessment, indicating that most penalties imposed in practice consist of fines that are too low to be effective. **Larger-scale violations are often met with disproportionately low fines**.[98] Enforcement effectiveness can also be measured by identifying the share of decisions that have been appealed – 0.6% for the reporting period that was evaluated in the 2018 REACH review.[99] This hints to the incentive situation of enforcement officers – and their supervisors – who aim to avoid taking risks, and as a consequence may shy away from dissuasive sanctions. Information gathered by Milieu shows a disproportionate use of lenient administrative follow-up actions instead of judicial proceedings.

The information provided by the Forum highlights critical weaknesses in the implementation of REACH Authorisation, serving as an important initial indicator. However, further investigation into the concrete enforcement practice of national authorities is needed to understand the magnitude of the problem fully — a task this report aims to address.

3.2 Analysis of country-specific enforcement date: the cases of France, Germany and Spain

Our in-depth analysis of enforcement practices in France, Germany, and Spain offers only partial access to the data needed for a comprehensive and objective evaluation of the state of enforcement of the

[94] Milieu Consulting (2009), Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States.
[95] Milieu Consulting (2020).
[96] Milieu Consulting (2020).
[97] ECHA (2023), REACH Enforcement Project (REF)-9 report.
[98] Milieu Consulting (2020).
[99] SWD(2018) 58 - part 5, 122.

Authorisation regime. While this limited transparency prevents a full understanding of how effectively REACH is enforced across these jurisdictions, it already reveals unequivocal indications of enforcement gaps.

3.2.1 France

Context

The French chemical industry is a key industrial sector counting around 4,000 companies and over 200,000 employees.[100] Many of these companies handle substances of high concern, with some operating under a REACH Authorisation.[101]

In France, the Directorate General for Risk Prevention (DGPR), under the Ministry for the Ecological Transition, is responsible for setting the strategic direction and actions to ensure that French companies comply with chemical regulations, including REACH. The more specific coordination of controls and inspections is delegated to regional authorities, known as DREALs (Regional Directorates for the Environment, Planning, and Housing), as well as local provincial units (at *département* level). In 2020, France reported that only 20 environment specialised inspectors are competent to monitor the enforcement of chemicals regulation including REACH.[102]

The day to day operation and regulatory compliance of "installations listed for the protection of the environment" (so-called ICPE), which are likely to pose a risk to third parties or the environment, is monitored by a dedicated inspection taskforce, called the ICPE police.[103] Today, there are around 500,000 installations listed as such, spread across French territory.[104] This taskforce's main mission is to "*prevent and mitigate nuisances and risks linked to industrial activities in order to protect people (residents, third parties) and the environment*".[105] It is particularly responsible for conducting on-site inspections, including those involving installations subject to REACH Authorisation.

France reported that, **since 2016, 5% of inspections of those installations must include "a chemical products component".**[106]

In addition to the ICPE police, other authorities are involved in monitoring compliance with REACH, including labour inspectors, customs, sanitary inspectors, the ministry in charge of competition policy, consumer affairs and fraud control, etc.[107]

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[100] See https://www.francechimie.fr/l-industrie-de-la-chimie.

[101] For example: ROQUETTE Frères (authorisation granted until 2028 for the use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin), Laboratoires Expanscience (authorisation granted until 2029 for the use of 1,2-dichloroethane as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients), Safran Aircraft Engines (authorisation granted until 2027 for the use of chromium trioxide based surface treatment mixture applied on safety critical rotating components of commercial and military aircraft engines). Many companies are known to operate (anonymously) under the CTAC upstream application.

[102] Milieu Consulting (2020), Table 38, p.74.

[103] Pursuant to Article L. 511-1 and Article L.172-1, Code de l'environnement.

[104] Direction Générale de la Prevention des Risques (2023), Bilan de l'action de l'inspection des installations classées sur l'année 2023 et perspectives pour l'année 2024.

[105] See https://www.ecologie.gouv.fr/politiques-publiques/savoir-icpe-nomenclature-gestion-declaration.

[106] Milieu Consulting (2020), 78.

[107] Article L521-13, Code de l'Environnement.

These inspectors may issue a formal notice identifying legal violations and setting a mandatory deadline for corrective actions.[108] The matter may then be referred to the relevant administrative authority – the prefect – who has the power to impose administrative sanctions, such as fines up to €15,000,[109] Some violations, such as the failure by a supplier to communicate accurate and updated chemical information via the safety data sheet or the retention of information crucial to evaluate compliance, may even warrant actions in the form of a criminal sanction, including jail time, closure of the activity and fines up to €75,000 (for individuals) or €375,000 (for legal persons).[110]

Recently, the government set up an online platform called '*Géorisques*' where inspection reports and subsequent follow-up actions can be made publicly available.[111]

On paper at least, the existing legal framework supports robust, dissuasive, and transparent enforcement. **In practice, however, the reality falls short.**

What we know

The most recent, publicly available, evaluation on ICPE-related inspection activities conducted in 2023 confirms the Ministry's commitment to monitor the implementation of recently granted authorisations.[112] This official report highlights that targeted inspection campaigns have been conducted, uncovering significant levels of non-compliance. For example, **in the Auvergne-Rhône-Alpes region, the main seat of France's chemical industry, 73% of sites inspected failed to meet the safety regulations for managing substances of very high concern.** The final findings reveal, for example, that "in nearly half of the inspected establishments, the requirements for properly sizing retention devices associated with chemical storage, loading, or unloading are not fully met". Despite these violations, only 4% of cases resulted in administrative orders from the relevant authority.[113]

Apart from this recent brief assessment, we know little about the state of enforcement of the REACH Authorisation in France, despite the supposed availability of data via the *Géorisques* platform.

The most exhaustive source of information on the state of enforcement in France originates from the 2020 Milieu Consulting report to the European Commission on the operation of Article 117 REACH (although it is not specific to the implementation of the Authorisation regime) and from the Forum REF-9 report. Some further data related to REF-9 was shared following the access-to-documents request we addressed to ECHA. ClientEarth also accessed information at a later stage, following an access to document request to the DGPR.

In the context of its reporting to ECHA and the European Commission **in 2020**, **France established that each year, the Competition, Consumer and Fraud Control Authority inspects between 1,000 and 1,300 establishments and carries out between 180 and 200 samples for both REACH and CLP.**[114] During the reporting period, the most controlled REACH requirements were restrictions (6,605) and supply-chain information (2,790); **compliance with authorisations represented only 190 of the total**

[108] Article L521-17, Code de l'Environnement.
[109] Article L521-18, Code de l'Environnement.
[110] Articles L521-21 à L521-24, Code de l'Environnement.
[111] See https://www.georisques.gouv.fr/.
[112] According to this report, 17 authorisation decisions were published between January 2016 and June 2023 for the use of 4 Annex XIV substances (mainly of which OPE (Octylphenols ethoxylated) and NPE (Nonylphenols ethoxylated)) by French companies.
[113] Direction Générale de la Prevention des Risques (2023), 16.
[114] Milieu Consulting (2020), 78.

number of controls. In 2019, over 20% of REACH-inspected companies did not comply with their obligations, including those related to authorisations, according to that reporting. Figures from this report cannot however be considered conclusive inasmuch as key terms (e.g. 'inspection') are not defined.[115]

The information presented in the REF-9 report is especially valuable, offering an in-depth look into the enforcement of the REACH Authorisation chapter. According to the report, **inspections conducted in France between 2017 and 2020 uncovered 21 instances of non-compliance,** the majority of which (14) involved large downstream companies—those with over 250 employees and an annual turnover exceeding €50 million. Aside from the two companies that used SVHCs without authorisation, **most cases of non-compliance related to the failure by companies to comply with the conditions set in the authorisation decision**, often due to a lack of information in the safety data sheet regarding matters such as the monitoring conditions, operational conditions and risk management measures that should be implemented on-site. A few companies also failed to comply with the obligation to notify ECHA within three months of the first supply of the substance (Article 66 REACH). **In 18 out of the 21 cases of non-compliance detected, competent authorities sent written advice to the company.** All cases were reported as "ongoing", making it impossible to determine whether any follow-up occurred, including potential penalties if non-compliance persisted after the written order. **An administrative order was issued in six cases, and in only two, the authorities considered imposing a daily penalty payment.**

Some of the information found via the *Géorisques* platform confirms the REF-9 project results. Notably, several companies were found to continue using substances of very high concern without prior authorisation or without proper risk management in place in accordance with the authorisation decision.[116] Access to enforcement data on REACH using this platform is extremely limited because it is impossible to filter by type of non-compliance or by authorisation granted. Despite the tool's goal of enhancing transparency, this limitation makes it practically impossible to get a precise understanding of the state of enforcement of the REACH Authorisation regime in France.

In June 2024 ClientEarth requested access to enforcement data from the past two and a half years from the unit in charge of chemicals policy at the DGPR. The Ministry initially responded that the information was held by regional authorities and was therefore not immediately available. Following an appeal to the national commission in charge of administrative documents (CADA)[117], the DGPR was instructed to provide us with the results of inspections conducted since 2021. We obtained access to 41 inspection reports where non-compliance with REACH Authorisation was identified, in addition to 3 letters of formal notice linked to some of the inspections.[118] This is a significant increase compared to the 21 cases reported in the context of REF-9 over the period 2017-2020. From these reports, it is however not possible to deduce the overall number of companies that were inspected, and how many of them actually complied with the Authorisation rules.

The companies that are the object of those reports are varied in size, from small and medium enterprises[119] to big companies such as Toyota, Airbus, ArcelorMittal and Sanofi. A significant number of

[115] See further on that, Section 3.3.
[116] For example: the companies Turdus Testers of Capacity, or SAFT (TOTAL subsidiary).
[117] See https://www.cada.fr/.
[118] See the supplementary material, 34 – 582.
[119] Such as Ferelec, Rabas Protec, Turdus Testers of Capacity, or Anabio.

those companies specialise in the surface treatment of metal and use chromium trioxide for that purpose, oftentimes under the upstream *Chemservice* authorisation granted in 2020.[120]

Our analysis of these reports aligns with previously noted assessments of enforcement actions in France. A first key observation is that **non-compliance often involves multiple breaches of the Authorisation regime.** The most common violations include breaches of Articles 31 (provision and content requirements for safety data sheets), 56 (compliance with authorisation conditions by downstream users, such as providing protective equipment to the workers[121]) and 66 REACH (duty to notify ECHA). For some companies, it is unclear whether they operate under a lawful authorisation.[122]

Additionally, **most follow up enforcement actions are focused on reminding the company of its obligations, asking for clarification and inviting them to comply, usually within a certain timeframe.** These reminders take various shapes.

In various cases the inspection report indicates that the situation is "*susceptible of consequences*": the company is then expected to clarify the situation and prove that it is complying with the regulation. The inspectors make such conclusions "*when it is not possible at the end of the inspection to rule on compliance, or for facts not involving safety and whose return to safety compliance can be quick*".[123] For example, a company failed to explain in precise terms the risk management measures it has put in place to reduce emissions into the air of potassium hydroxyoctaoxodizincatedichromate (zinc potassium chromate) in accordance with the authorisation decision, but simply referred to the measures included in the chemical safety report of their supplier.[124] It is unclear why some cases that clearly pertain to safety, e.g. when a company simply fails to implement a system to monitor emissions of chromium trioxide into air[125], are merely "*susceptible of consequences*".

In other instances, the reminder adopts a more formal tone: various companies have received a follow-up letter from the responsible prefect (referred to as a "*lettre de suite*") or a formal notice ("*mise en demeure*"). The latter carries greater legal weight, as failure to comply with the directives outlined in a formal notice can, in theory, result in immediate administrative or criminal sanctions. Such notices were issued in 7 cases (out of the 41 inspections conducted), following inspections that noted, for instance, failures to notify ECHA about worker exposure scenarios[126] or to operate under a lawful authorisation.[127]

The most recent reports - since early 2024 - seem to propose a more gradual approach to enforcement. When a breach is detected, companies can be asked to implement corrective actions or to justify a situation of non-compliance, before any administrative follow up takes place.[128] In some circumstances, this approach may seem ill-suited to the seriousness of the breach. For instance, the laboratory Anabio (inspection dated 02.04.2024) was asked for 'corrective action' after inspectors noticed that the company

[120] Commission Implementing Decision of 18.12.2020 partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Chemservice GmbH and others).
[121] For example: LRB ROULIER, DREAL Ile-de-France report of 29.07.2022 for inspection dated 22.06.2022.

[123] This reminder on what follow up actions can be considered can be found on each inspection report.
[124] SAFRAN NACELLES, DREAL Normandie report of 31.01.2023 for inspection dated 29.11.2022.
[125] LES STRATIFIES, DREAL Hauts de France report of 17.01.2022 for inspection dated 17.12.2021.
[126] KERBIRIO, DREAL Ile-de-France report of 25.04.2024, for inspection dated 10.05.2022.
[127] PROTEC Industrie, DREAL Ile-de-France report of 13.04.2022, for inspection dated 10.02.2022.
[128] For example, BIOCHENE, DREAL Bretagne report (missing date) for inspection dated 02.04.2024; Techniques Surfaces Andrezieux, DREAL Auvergne Rhone-Alpes report of 26.02.2024 Inspection dated 16.02.2024; ANABIO, DREAL Bretagne report of 11.04.2024 for inspection dated 02.04.2024.

did not implement a proper elimination system for the residues of 4-tert-Octylphenol, an endocrine disruptor, which ended directly in the sewage system.

Beyond written advice, follow-up letters from the prefect and formal notice, **none of the inspection reports suggest that more substantial sanctions, such as a fine, were ever considered – even in the worst cases, such as a failure to respond in time to a formal notice[129] or repeated non-compliance.**[130] Furthermore, the inspection reports do not clarify whether any sanctions were imposed after the compliance deadline stipulated in a formal notice had passed. Follow-up inspections show that some of the companies who received formal notice, i.e. the strictest form of reminder to comply, implemented the necessary steps to comply with the authorisation.[131] **That is a further indication of the importance of implementing dissuasive enforcement tools: the strongest sanctions provide the biggest incentive to comply**.

3.2.2 Germany

Context

In Germany, the chemicals industry is a key industrial sector, with a turnover of around €225.5 billion and employing around 479,500 people.[132] **This makes the chemicals industry the third-largest industry in Germany, behind the automotive industry**, and machinery and equipment.[133] Several of the approximately 2,100 chemicals companies in Germany handle chemicals which are subject to Restrictions or Authorisation under REACH.[134]

The 16 individual states (*Länder*) are responsible for REACH enforcement in Germany.[135] The Länder authorities are responsible for carrying out regular inspections regarding REACH compliance. They have their own enforcement priorities and projects.[136] The types of authorities involved vary, including

[129] See CIN Monopole, DREAL Auvergne Rhone-Alpes report of 26.07.2024 for inspection dated 07.06.2024. The report notes that "*Even if the Cin Monopol company was not able to respond to the inspection on time, the inspection found that the company had made efforts to comply*
particularly concerning the development of SDSs for dangerous products distributed. However, ***the actions relating to the transmission of these SDSs have not been completed.*** *The transmission proof is necessary to allow the formal notice on this obligation to be lifted.* ***The inspection expects more responsiveness and commits the company to making its internal organizations on these two subjects, in particular because Cin Monopol distributes products strictly regulated chemicals*** *and that the company must play an essential role in the transmission of information to its customers, for the protection of health and the environment*." [translated from French to English]

[130] MECACHIMIQUE, DREAL Ile-de-France unite départementale du Val d'Oise report of 27.11.2023 for inspection dated 02.11.2023.

[131] For example, see the case of PROTEC Industrie, DREAL Ile-de-France Report of 31.05.2023 for inspection conducted on 10.05.2023.

[132] Verband der Chemischen Industrie e.V., 2024 Chemiewirtschaft in Zahlen.

[133] Cefic, Germany – Key Facts.

[134] For example, BASF (authorisation for the industrial use as solvent and crystallisation medium in the synthesis of the plant protection active substance bentazone and the biocidal active substance flocoumafen until November 2029), SAXONIA Galvanik GmbH (authorisation for the use of chromium trioxide for plating on plastics for automotive applications until November 2029), Liebherr-Aerospace Lindenberg GmbH (authorisation for the use of sodium dischomate for Sealing after anodising of aluminium alloys and passivation of metallic coatings of actuation and landing gear system parts for the aviation industry that meet the airworthiness certification requirements until December 20234).

[135] See Zoll online - Allgemeine Informationen - Liste der für das Chemikalienrecht zuständigen Landesbehörden.

[136] Milieu Consulting (2020), 78.

agencies, district offices and regional councils. Several Länder have also created authorities with specific geographical or thematic competence.

The Federal Institute for Occupational Safety and Health (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin*, *BAuA*), an agency within the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (*Bundesministerium für Umwelt, Naturschutz, nukleare Sicherheit und Verbraucherschutz*, *BMUV*), provides informal support via one of its departments, the Federal Office for Chemicals (*Bundesstelle für Chemikalien*). The Federal Office for Chemicals also acts as the interface for contacts with other Member State authorities and ECHA and advises the federal government on REACH-related matters.

The BAuA established the working group for chemical safety (*Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit, BLAC*) with the objective of facilitating coherent and consistent enforcement of chemicals legislation across the Länder, including by issuing guidance on REACH enforcement.[137] This is also why the competent authorities in the Länder tend to hyperlink the BLAC website for further information.

In addition, the Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung, BfR*), and the German Environment Agency (*Umweltbundesamt, UBA*) may be consulted and provide input.[138] The German Central Customs Authority (*Zoll*) monitors the import and export of chemicals, including trade in substances subject to REACH Restriction and Authorisation.[139]

Data on the budget and staff allocated to REACH enforcement in Germany is unavailable.[140]

When the competent state authorities identify a breach, they may take appropriate measures, including requiring corrections to labelling or Safety Data Sheets, withdrawal or recall of the product, as well as fines. Goods which are the subject of a breach of REACH, such as those not duly registered before they are manufactured or placed on the market, can be seized by the authorities.

Breaches of REACH are punishable by up to five years imprisonment or a fine depending on the severity and context of the breach.[141]

What we know

The relevant authorities do not appear to publish REACH enforcement decisions or statistics.

Data on REACH enforcement in Germany for the period of 2015 to 2019 are available in a European Commission report, however: according to the report, Germany carried out between 6,122 and 8,442 REACH controls (inspections, investigations, monitoring, or other enforcement measures) each year. Overall, 6% of controls carried out by German authorities concerned manufacturers, less than 1% concerned representatives, 34% concerned distributors, 32% concerned downstream users, and 9% concerned importers.[142]

[137] Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit (BLAC).
[138] See Section 4(1) of the German Chemicals Act (Chemikaliengesetz).
[139] Zoll, Allgemeine Informationen – Chemische Stoff, Zubereitungen und Erzeugnisse.
[140] See Milieu Consulting (2020), 74.
[141] Section 27b of the German Chemicals Act.
[142] Milieu Consulting (2020), 92; the report does not specify which other controls were conducted to reach 100%.

In 2019, German authorities identified breaches in 35% of those controls, a significant rise from only 19% in 2015.[143] The type of non-compliances identified included failure to comply with: registration requirements (12%); dossier evaluation requirements (12%); data-sharing duties (43%); information obligations in the supply chain (56%); requirements related to substances in articles (13%); authorisations (13%), and restrictions (20%), with some controls identifying multiple instances of non-compliance.[144]

While exact numbers are unavailable, Germany and Sweden made up three quarters of the total number of breaches of REACH referred to a public prosecutor's office in the EU and EEA.[145] Germany also reported that between 2015 and 2019, an average of only two REACH enforcement decisions were appealed each year and only one was overturned in that period.[146]

Aside from this brief assessment, **very limited information on the state of REACH enforcement in Germany is available**. This is also recognised, for example, by a report published by the German Federation for the Environment and Nature Conservation (*Bund für Umwelt und Naturschutz Deutschland e. V., BUND*), which states that data on enforcement actions with respect to chemicals and product safety law in the context of e-commerce are not available.[147]

A report on compliance with REACH Authorisation requirements in Germany published by BLAC in 2023 provides additional details.[148] The **report reflects the data collected in Germany as part REF-9**.[149] While the focus of the report is the state of compliance with REACH rather than the state of enforcement by the authorities, it provides some interesting insights.

According to the report, the authorities participating in the study **carried out 77 checks of 11 different substances subject to authorisation in 70 companies across 13 (out of the 16) Länder** – within a whole year (2021). Even when we acknowledge that additional relevant enforcement activities may have taken place during that period which were not reported to the ECHA project, the figure seems to indicate the small scale of the controls conducted.

As regards placement on the market, in 58% of cases, the substance was placed on the market with a valid authorisation.[150] In 25% of cases the substance benefitted from an exemption (for R&D, on-site isolated intermediates, or other reasons). As regards use, in 73 out of 77 cases substances for which the sunset date had passed were being used, and 67% were being used with a valid authorisation.[151] 22% of checks concerned substances benefiting from an exemption.[152]

While in 40 cases, the authorisation conditions were found to be fully sufficient for effective enforcement,[153] inspectors flagged the following challenges in relation to enforcement of the conditions

[143] Milieu Consulting (2020), 87.
[144] Milieu Consulting (2020), 99.
[145] Milieu Consulting (2020), 104.
[146] Milieu Consulting (2020), 106-107.
[147] Bund für Umwelt und Naturschutz (2023), BUND -Rechtsgutachten – Überwachung der Einhaltung des Chemikalien- und Produktsicherheitsrechts im Online-Handel.
[148] BLAC (2023), REF-9-Projekt des Forums Überprüfung und Überwachung der Erfüllung der Anforderungen der REACH-Zulassungspflichten – Abschlussbericht zu den Ergebnissen in Deutschland (REF-9 Report Germany).
[149] ECHA (2023), REACH Enforcement Project (REF)-9 report.
[150] REF-9 Report Germany, 13.
[151] REF-9 Report Germany, 14.
[152] REF-9 Report Germany, 14.
[153] REF-9 Report Germany, 15.

set out in the authorisation decision: (i) the fact that the authorisation decision was in English and its application is complex; (ii) the descriptions of the process categories in the extended safety data sheet lack the necessary detail and inspectors had to use the chemical safety report; and (iii) in some cases the authorisation decision was not clear on the deadline applicable to downstream users.[154] The safety data sheet, followed by the succinct summary and the chemical safety report were the most accessible sources of information, according to the report.[155]

The report states that breaches of the REACH Regulation have been identified in 25% of 77 cases – with downstream users being responsible for the largest number of breaches.[156] Among the 70 businesses checked, 27% did not comply with all their REACH obligations.[157] A 25% or 27% non-compliance rate is not acceptable, not least given the high stakes in the Authorisation context. Yet it is lower than the 40% rate at EU-level.

As to the specific REACH obligations breached **most often, 23% of breaches identified concerned Article 56(2) – which requires using the substance in accordance with the conditions of an authorisation granted to an actor upstream in the supply chain for that use**. 16% of breaches were violations of Article 31 (provisions regarding safety data sheets), and 13% of breaches related to Article 37(5) (duty to identify and apply risk reduction measures). The remaining breaches concerned other provisions.[158] Only 2% concerned breaches of the authorisation obligation in Article 56(1) – i.e. the actual authorisation requirement.[159] In terms of the substances, most breaches identified related to trichloroethylene, chromium trioxide, strontium chromate, and 1,2 dichloroethane.[160]

The measures taken by the authorities in response to breaches of REACH provide an interesting overview of the measures typically adopted for enforcement. **In the 21 cases in which at least one enforcement measure was adopted, 17 written notices and 5 oral notices were issued. A fine was imposed in only one case** and two cases were referred to the public prosecutor. Six other measures were adopted but no administrative orders were issued.[161] In 23 cases, further actions initiated during the inspections were still pending at the time the study was concluded.[162] An earlier report from BLAC, relating to a study carried out in 2020, also showed that the most common measure adopted in response to an authority identifying a breach of REACH, was a written notice.[163]

But the **reality of enforcement conducted on the ground by German authorities stands in sharp contrast to the power they are granted by law**. The enforcement authorities in the Länder have the power to impose measures necessary to eliminate non-compliance and to prevent future non-compliance by means of administrative order.[164] If the administrative order is not complied with by the deadline given, the authority may, for a limited period, either fully or partially, prohibit the activity which is

[154] REF-9 Report Germany, 15.
[155] REF-9 Report Germany, 17.
[156] REF-9 Report Germany, 18.
[157] REF-9 Report Germany, 20.
[158] REF-9 Report Germany, 18.
[159] REF-9 Report Germany, 18.
[160] REF-9 Report Germany, 20.
[161] REF-9 Report Germany, 20.
[162] REF-9 Report Germany, 20.
[163] BLAC (2022), REF-8-Projekt des Forums Durchsetzung der REACH-, CLP- und BPR-Pflichten in Bezug auf im Onlinehandel verkaufte Stoffe, Gemische und Erzeugnisse.
[164] Section 23(1) of the German Chemicals Act.

the subject of the administrative order if this is necessary to protect the life and health of employees.[165] The authority may also impose restrictions on the manufacture, placement on the market, or use of substances, mixtures, and articles which may release or contain a hazardous substance or mixture if there are indications that they pose a significant danger to human or environmental life or health.[166] Such administrative orders can only be imposed if they are compatible with EU law.[167] Similarly, under the Hazardous Substances Ordinance (*Gefahrstoffverordnung*, *GefStoffV*), the authority may impose measures on a manufacturer, supplier, or employer on a case-by-case basis to enforce certain REACH-related obligations, such as obligations related to the safety data sheet and restrictions. These may include, in particular, requiring a company to adopt measures to combat particular hazards, determine whether a suspected hazard actually exists and what measures must be adopted to combat it, or stop the activity which puts employees at risk if the employer does not take the measures (in a timely manner) which are necessary to address the danger.[168] The authority may even prohibit an employer from carrying out activities involving hazardous substances or order the affected workplace to be shut down if the employer fails to communicate the results of a risk assessment and the underlying data to the authority when required to do so.

So while there are tools with teeth in the toolbox of German enforcement, the authorities almost exclusively pick the softest of measures: issuing a notice. Given the non-compliance rate of 25% in Germany, it is highly doubtful that the mere existence of stricter tools has a sufficiently deterrent effect. Rather, these need to be employed more frequently.

3.2.3 Spain

Context

The Spanish chemical industry is a key industrial sector counting around 3,100 companies and more than 792,000 employees, of which 233,000 are direct employees. Its importance as an economic driver for Spain is reflected in its contribution of 6.1% to national GDP. It also accounts for 5.5% of the country's private-sector salaried workforce when considering indirect and induced effects, and 14.3% of industrial GDP.[169]

In Spain, REACH enforcement is regional: REACH is enforced by 17 Autonomous Communities, and two Autonomous Cities, hereinafter referred to as '**Regions**'. Enforcement varies depending on the products concerned. **Health issues** are dealt by regional health departments (*Consejerías de Sanidad)* which exchange information and coordinate their enforcement among themselves and with the Ministry of Health through the National Network for Monitoring, Inspection and Control and the Fast Track Chemicals Information Exchange System (*Red Nacional de Vigilancia, Inspección y Control y del Sistema de Intercambio Rápido de Información sobre Productos Químicos*). **Environmental issues** are coordinated among the Regions by the Ministry for Ecological Transition and the Demographic Challenge (*Ministerio para la Transición Ecológica y el Reto Demográfico*).

[165] Section 23(1a) of the German Chemicals Act.
[166] Section 23(2) of the German Chemicals Act.
[167] Section 23(2) of the German Chemicals Act.
[168] Section 19(3) of the German Hazardous Substances Ordinance.
[169] See https://www.feique.org/el-sector-en-cifras/.

Spanish REACH enforcement is provided for in Law 8/2010[170] and in complementary regulations passed by each Region where these exist. However, regional complementary regulations on enforcement could not be identified. Law 8/2010 provides, among other things, a list of penalties for infringements which can amount to fines up to a maximum of €1.2 million.[171]

What we know

The REF-9 report from 2023 explains that in Spain, 23 companies have been inspected in relation to 38 substances.[172] Yet the results of these inspections are not traceable as data from all participating Member States have been aggregated. The latest Member State report on REACH implementation and enforcement published in 2020 and covering the years 2015-2019 notes for Spain 8,113 'controls' in the context of Authorisation.[173] Out of these, 548 found non-compliance resulting in a rate of non-compliance at 7%.[174]

Additionally, on 21 June 2024, in response to a request made by ClientEarth, the Spanish Ministry of Health provided a list containing the number of official controls of REACH compliance. However, as regards authorisations, the document refers to the 8,113 controls carried out between 2015 and 2019, i.e. the same figures published in 2020. The response by the Ministry does not specify the nature of the controls, the measures taken to address the infringements (if any), or any fines or sanctions imposed (if any). The Ministry of Health mentions that it does not have such detailed information.

Furthermore, **the Ministry of Health asserts that the information it holds is limited to data originating from 'REACH ENFORCE' projects that were designed and coordinated by the ECHA Forum**. Thus, it does not contain information on the general enforcement activities carried out by the Regions that may – or may not – go beyond Forum activities. Desk research did not identify additional publicly available information on enforcement activities. While each regional enforcement authority provides databases making it possible to search for decisions at the regional level,[175] **REACH enforcement decisions have not been identifiable, suggesting that these may not be publicly available**.

3.3 Oversight by the authorities

Section 2 concluded that to fulfil their respective roles in the Authorisation system, both the Commission and ECHA must be fully informed about the state of play of implementation, including enforcement taking place and its results. This section considers the actual level of awareness when it comes to violations in relation to REACH authorisations. To this end, it will look at the periodically generated data by Member States and the responses ClientEarth received to access-to documents requests.

[170] Ley 8/2010, de 31 de marzo, por la que se establece el régimen sancionador previsto en los Reglamentos (CE) relativos al registro, a la evaluación, a la autorización y a la restricción de las sustancias y mezclas químicas (REACH) y sobre la clasificación, el etiquetado y el envasado de sustancias y mezclas (CLP), que lo modifica.
[171] Article 7, Law 8/2010.
[172] ECHA (2023), REACH Enforcement Project (REF)-9 report, 23.
[173] Milieu Consulting (2020), 98.
[174] Milieu Consulting (2020), 99.
[175] These include the Official Journals and Transparency Portals of each region (e.g., in Madrid, the general databases are BOCM and Transparencia Madrid).

3.3.1 Data available through reporting at the EU level

REACH requires Member States to submit a report to the Commission that has to cover REACH enforcement, including "*the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken*".[176] The Commission makes these reports available to the Forum.

The report is due every five years, i.e. three times since the adoption of REACH, in 2010, 2015 and 2020, with the fourth reporting period ending in 2024. The information provided by Member States helps the Commission to understand structural aspects (e.g. organisation of enforcement at country level), for example, and how Competent Authorities are coping with their obligations related to REACH evaluation and risk management.

In terms of enforcement, the data provided for the most recent reporting period – published in 2020 – cover, inter alia:[177]

- the number of controls reported as relating to authorisations and
- the number of cases of non-compliance found identified as authorisations, as well as the rate of non-compliance.

Member States submit the data in an aggregated, i.e. anonymised way.[178] Hence, **the Commission receives only figures, without information which would allow it to precisely determine which relevant provisions have been violated and which measures the enforcement agency has taken, let alone the identification of an actual case.**

The reports otherwise lack clarity and robustness. There are no legally binding definitions for key terms, such as 'official inspections' which trigger reporting requirements under Article 127. For example, if an enforcement officer checks the proper labelling of paint varnishes on sale in a DIY store, this may involve different products from the same or separate holders of legal duties, under CLP, REACH and potentially other legislation. Yet the data submitters decide to what extent each of these checks constitute 'official inspections' of their own. Each Member State follows its own logic; there is no harmonisation. Hence, the reader cannot get a proper impression of the activities in a particular Member State, rendering comparisons of data from different Member States is impossible. To make things worse, the Member States apply different enforcement strategies, which are not presented transparently in the report.

Furthermore, **the reporting interval set at five years is too long.** In this respect, ECHA noted in 2021 that the absence of enforcement data "*on an annual basis is hampering the creation of a full continuous picture of what enforcement is taking place in the EU, and thereby also not providing the best information base for Forum itself to focus its harmonisation efforts where they could add most value*". From the Member States' perspective they have to collect the data anyway so a shorter reporting interval would arguably not create any additional administrative burden.

To prepare for the coming report and make sure all relevant data are collected, Member States use the previous reporting structure as their orientation. This is necessary as the Commission does not inform the Member States at the beginning of each interval which data endpoints will have to be reported, but

[176] Article 117(1) in conjunctions with Article 127, REACH.
[177] Milieu Consulting (2020).
[178] See the examples here Progress reports on evaluation and enforcement of REACH in Europe | ClientEarth.

only does so towards the interval's end when the next reporting deadline is looming. Whether or not Member States will be able to adequately respond to any new item therefore depends on happenstance (i.e. if they collected the respective data in any case) or the feasibility of retroactively chasing this additional information.

3.3.2 Responses received to access-to-documents requests

In June and July 2024, ClientEarth requested that the European Commission, ECHA and the Competent Authorities in three Member States (Germany, Spain, France) grant access to documents containing information the respective authorities hold on violations of Authorisation obligations detected since January 2022 in those three countries.[179]

Responding to the request, the **Commission** stated that, in the relevant period, i.e., over two and half years, it did not receive any reports on inspections from the national authorities in Germany, France or Spain showing non-compliance with Authorisation provisions, nor is it aware of decisions on enforcement actions taken by those national authorities when non-compliance has been identified.[180]

The Commission also confirmed that it has thus far never withdrawn an authorisation after having identified non-compliance.[181]

ECHA stated in its response to ClientEarth's access-to-documents request[182] that it holds a "*Dataset with results of inspections carried out by France, Germany, and Spain in the context of REF-9 project which identified non-compliance with Articles 31, 37, 56, 65, 66 of REACH*". This relates to the raw data submitted by Member States participating in the project, which is specific to each individual inspection case and therefore provides a much greater level of detail compared to the aggregated data published in the final REF-9 report. However, the operational phase of the REF-9 project ran from January to December 2021.[183] By not referring to additional data, ECHA confirms they are not aware of any violations that took place between the start of 2022 and mid-2024. The Agency moreover expressly confirms in other correspondence[184] that while "*there are minutes of meetings of the Enforcement Forum, none contain exchanges on noncompliance with authorisation obligations*".

As for the **Competent Authorities (CA),** Germany responded that the information requested was not available to them.[185] The German CA noted that the Länder in charge of enforcement "*possibly*" hold the requested data.

Spain's CA only provided the number of controls carried out under REACH and CLP, including authorisations, covering the years 2015-2019. This data was derived from 'REACH ENFORCE' (i.e. Forum) projects – hence data that were outdated and so outside the scope of the request.[186]

[179] See the supplementary material.
[180] See the supplementary material, 2.
[181] In its the reply, the Commission referred to four decisions amending an authorisation and additional seven decisions repealing decisions, both in the context of a review under Article 61 REACH. None of these reviews seem to have been triggered by legal infringements detected during enforcement. In one case RAC found that the applicant did not comply with the conditions – but new authorisation was still granted (C_2024_6_EDC_Eurenco).
[182] See the supplementary material, 5.
[183] ECHA (2023), REACH Enforcement Project (REF)-9 report, 20.
[184] See the supplementary material, 20.
[185] See the supplementary material, 585.
[186] See the supplementary material, 591.

Despite its centralised administrative structure, France's management of enforcement data is not fully centralised and the country relies heavily on regional authorities to conduct REACH-related inspections. Both reasons may explain why, similar to Spain and Germany, it was unable to provide the requested information immediately and replied that it needed to consult the relevant authorities. It is only because ClientEarth requested an opinion from the CADA that the DGPR ultimately shared the requested information.

Furthermore, some data became available through our request to ECHA, offering additional transparency regarding the information France submitted for the REF-9 project.[187] The *Géorisques* platform represents an effort towards greater transparency in France. While this platform does not yet offer a complete view of enforcement activities and has accessibility limitations, it marks a significant step toward centralising enforcement-related information and making it more accessible to the public.

Most of the information that was shared with ClientEarth following the access-to-document request can be found on *Georisques* – however, without such a request, it would have been practically impossible to access this information. Furthermore, without appealing to the CADA, it is likely that the DGPR would not have disclosed this information, highlighting a significant and unwarranted lack of transparency. While the inspection reports provided valuable insights into the enforcement of the Authorisation regime, by showcasing very concrete and specific examples of non-compliant operators, they present an incomplete picture. A key limitation is the inability to determine from these reports whether follow-up sanctions, such as those resulting from formal notices, were issued. Additionally, partly due to the narrow scope of our access-to-documents request, these reports fail to provide a comprehensive overview of the enforcement landscape in France. Specifically, they do not shed light on the total number of controls conducted that specifically relate to the Authorisation regime or the overall compliance rate.[188]

3.3.3 Knowledge appears to be limited

In the area of enforcement, REACH only provides for a few principles to be followed at the Member State level (e.g. penalties that are "*effective, proportionate and dissuasive*"). However, REACH does not specify anything related to the quantity or quality of inspections. Rather, it provides for a reporting scheme that was intended to enhance transparency of enforcement activities. Despite the initial objectives, the information gathered in these reports currently allows neither the Commission nor the Forum to monitor the state of play in terms of violations of the Authorisation requirements, nor does it make it possible for them to intervene in particular cases.

Informed by the responses to ClientEarth's access-to-documents requests, the reality check shows that neither the Commission nor ECHA have knowledge of concrete cases of non-compliance in the period at issue. Even the Competent Authorities contacted either do not directly possess this information – according to the replies we received – or they refused to share it.

In the cases of the Commission and ECHA, the lack of information could be explained if no enforcement had happened during that period. That is not possible, though, as there is evidence that at least in France the authorities have detected severe violations in the timeframe under investigation. If enforcement took place it is highly likely that violations were detected, given the high non-compliance rates identified in the REF-9 project (40 %). We can therefore conclude that **enforcement is taking**

[187] See the assessment in Section 3.2.1.
[188] See the assessment in Section 3.2.1.

place, but ECHA (Forum) and the Commission are failing to take note of the trends, the challenges, and the individual cases which may necessitate a strong regulatory response.

In legal terms, following the assessment set out above, **a (severe) breach of an authorisation decision is an event that changes the "*circumstances*" of an authorisation** and should thus trigger, or at least inform, the review or direct withdrawal of the authorisation by the Commission. However, it **is obvious that for the last two and a half years the Commission did not monitor such cases and, therefore, it failed to fulfil the responsibility conferred on it by REACH**.

As for the Forum in particular, considering its mission and mandate, it is hard to understand ECHA's insistence that no exchanges on violations of Authorisation rules were noted during the Forum meeting. It is difficult to imagine what the experts are discussing during those meetings.

As for Germany and Spain, there are two possible explanations, one being ignorance, just like in the case of the Commission and ECHA. The other explanation could be that during the last two and half years no enforcement of authorisations took place. This could not be verified.[189] The mere lack of oversight by the central CAs supposedly responsible for the implementation of Articles 125 and 126 of REACH is by itself highly problematic. And it raises the question of the relevance of the "*enforcement strategy at state level with own enforcement priorities and projects"* which Germany flagged to the Commission in one of its reports.[190]

3.4 Secrecy around enforcement

The replies received in response to ClientEarth's access-to-documents requests, or in some cases absence of a reply, expose how the authorities in charge of steering enforcement at national and EU level know little about violations of the Authorisation regime (see previous Section).

The handling of ClientEarth's access-to-documents requests also shows unwillingness by the institutions or in some instances strong pressure from the Member States not to share this information with the public, despite its public relevance and the related transparency obligations under the Aarhus Regulation and EU law.

The lack of transparency clashes with the fundamental right of access to documents recognised by the Charter of Fundamental Rights and in particular, with the right of the public to access environmental information. It is settled CJEU case-law that in principle the public must be given the widest possible access to documents and any exceptions applied must be interpreted strictly.[191] However, the responses we received demonstrate strong resistance to any degree of transparency in some Member States when it comes to enforcement of the REACH Authorisation regime. The following chapter will summarise and then analyse the arguments presented by different authorities in response to the access-to-documents requests.

Full correspondence with the relevant authorities can be accessed via the supplementary material.

[189] To this end, more access-to-documents requests would have been needed at the regional levels.
[190] Milieu Consulting (2020), 78 (emphases added).
[191] CJEU, Case C-64/05 P Sweden v Commission, para. 66; C-506/08 P Sweden v MyTravel and Commission, para. 75 and C-60/15 P Saint-Gobain Glass v Commission, para. 63.

3.4.1 ClientEarth's access-to-documents requests

On 7 June 2024, ClientEarth filed an access-to-documents request with ECHA requesting access to:

"1. Any documents received or produced by the ECHA since 1 January 2022 containing information on cases of non-compliance with authorisation obligations pursuant to Articles 60 and 66 REACH, both read in conjunction with Article 56 REACH, by economic operators in France, Germany, and Spain.

2. Minutes of meetings of the Forum for Exchange of Information on Enforcement (Enforcement Forum) produced since 1 January 2022 containing exchanges on noncompliance with authorisation obligations by economic operators in France, Germany, and Spain".

In its initial response of 23 July 2024, ECHA granted partial access to some enforcement data from France.[192] However, ECHA denied access to three types of information: own authorisation numbers, downstream authorisation numbers, and NACE codes. This information, according to ECHA, would make it possible to identify the specific company inspected either directly (in the case of own authorisation numbers and downstream authorisation numbers) or because it identifies a sector that may be very narrow (in the case of the NACE code), which in combination with other information that has been made public could lead to the identification of the specific company inspected. ECHA argued that the disclosure of information leading to the identification of a specific company which was inspected and found non-compliant would harm the commercial interests of that company. So ECHA based its decision to deny access on the need to protect the commercial interests of natural or legal persons under the first indent of Article 4(2) of Regulation 1049/2001.

ECHA did not disclose any information in relation to inspections in Spain and Germany, based on the objections received from these Member States. The decision did not explain the nature of these objections.

ClientEarth challenged ECHA's decision, to which the Agency responded on 25 September 2024 with a Confirmatory Decision. This decision elaborated on the nature of Germany's and Spain's objections to disclosure of any documents related to national enforcement. Similar to ECHA and France, these Member States also invoked the protection of commercial interests. As Germany puts it: *"The identification of a specific company would seriously undermine the companies' business interest, as a potential non-compliance could negatively affect business and commercial relations between the company in question and other businesses and consumers*".

In the Confirmatory Decision ECHA also referred to additional arguments raised by Germany and Spain in which they express their concern that granting access to the requested documents may have negative effects on their possibility of conducting effective enforcement:

"*The Spanish representative concluded that disclosing any document containing raw data from inspections related to REACH enforcement projects may impact negatively on the level of detail given by inspectors or directly on the willingness to participate by its regional enforcement authorities in future Forum projects*".

In addition, "*[t]he German representative stated that its enforcement approach invites and fosters a willingness of companies to share information and data with national enforcement authorities (NEAs) without inspectors requiring an administrative written order. This significantly increases the efficiency and*

[192] See the examples in Section 3.2.1.

effectiveness of NEAs' enforcement actions. If NEAs were asked to share or publish enforcement data, this would be detrimental to the level of cooperation that companies generally show towards NEAs. Duty holders would be less open to contribute, and NEAs would in turn need to rely on stronger, but less efficient enforcement measures. Hence, it is important for German NEAs to maintain the current level of trust, which includes trust that the data, which is provided to NEAs during enforcement actions, is protected".

Both Member States also refer to national (and regional) access-to-documents legislation applicable in their respective territories. The Spanish law justifies non-disclosure of the requested documents under the general presumption of secrecy in respect of surveillance, inspection and control activities. German law, in turn, bases non-disclosure on the need to protect confidentiality and professional secrecy.[193]

In addition, ECHA noted that the German representative informed the Agency that Germany might reconsider its participation in ongoing and future cooperation between Member State inspectors and ECHA itself if the requested data were disclosed. According to the Confirmatory Decision, all three Member States also noted that providing the requested data would likely directly impact the number and "*depth*" of inspections carried out at the national level in many Member States and would undermine the Forum's efforts to harmonise enforcement.

In light of these statements, ECHA identified a "*foreseeable and non-hypothetical risk that disclosure would lead to Member States not taking part in future Forum projects*". This in turn could result in a decreased number of inspections and weaker enforcement. Accordingly, ECHA states that under Article 4(2) third indent of Regulation 1049/2001, it must refuse access to a document in case disclosure would undermine the protection of the purpose of inspections, investigations, and audits.

3.4.2 Transparency as a risk to enforcement

Firstly, it is clear that both ECHA and some Member States prefer to keep information about enforcement away from public scrutiny. One of the two arguments raised by ECHA and Member States is the protection of the purpose of inspections, implying that transparency may risk effective enforcement. This reasoning however does not appear plausible: disclosure of enforcement activities could only impact the numbers of controls *reported* in the framework of coordinated enforcement projects, but not necessarily the number of controls performed.

The concern in the case of Germany and Spain that disclosure of any enforcement information whatsoever will undermine enforcement activities suggests their enforcement agencies have weak powers either in law or practice. If access to commercial operators or the information they disclose can be significantly undermined by the disclosure of certain information to the public, this suggests that enforcement authorities are granted insufficient access and investigative powers to carry out meaningful enforcement in the face of resistance from certain operators. While we agree that information on individual inspectors and their personal notes should legitimately be kept confidential to protect personal data and their professional activities, the same cannot be applied to the broader results of the inspections, the nature of violations, and the penalties applied. Enforcement by its very nature implies the ability of the enforcement authorities to take the necessary steps to ensure compliance with EU and national law, in this case, the REACH Authorisation regime. Although we acknowledge the importance of supporting and enhancing cooperation with companies, under no circumstance should this approach

[193] See the supplementary material, 20.

impede transparency of enforcement practices or shield wrongful behaviours, which would weaken enforcement. Effective enforcement must not be entirely dependent on such cooperation.

Secondly, the objections raised by ECHA and the Member States do not withstand scrutiny from the perspective of EU law.[194] Germany and Spain argue that national legislation would bar them from disclosing relevant documents. However, national rules cannot introduce new exceptions to access to information and thus narrow the scope of access to documents established under Regulation 1049/2001.[195] Any deviation could constitute an infringement of EU law.

Complete rejection of disclosure by Germany and Spain is highly problematic not only in light of the principle of granting wide access to documents, but also for their failure to consider the nuanced document-specific application of the exceptions they cite. Both authorities fail to consider whether it would have been possible for them to grant at least partial access to the requested documents, i.e. to data not related or potentially leading to the identification of individual companies.

Their disproportional approach is evident when compared with the approach taken by France.

3.4.3 Non-compliance is not a protected commercial interest

Similarly, **the protection of commercial interests should not be used to deny access to enforcement information.** The General Court of the EU has stated that "*it is not possible to regard all information concerning a company and its business relations as requiring the protection which must be guaranteed to commercial interests under the first indent of Article 4(2) of Regulation No 1049/2001 without frustrating the application of the general principle of giving the public the widest possible access to documents held by the institution*".[196] Therefore, clearly, not all information concerning a company and its activities falls under the exception of the first indent of Article 4(2) of Regulation 1049/2001.

The exception for commercial interests should be used to protect specific information that is unique to the company and could be used by competitors to gain an unfair advantage. The General Court has interpreted the notion of commercial interests under the first indent of Article 4(2) of Regulation 1049/2001 on multiple occasions. Generally, to fall within the exception for protection of commercial interests, the documents must contain information unique to the expertise, commercial strategies, or business relations of the company in question that, if disclosed to competitors, could be used to undermine competition or gain profit. The General Court has found that "*commercially sensitive information relating, inter alia, to the commercial strategies of the undertakings involved or to their customer relations or (…) information particular to that undertaking which reveals its expertise"* would fall under that exception.[197] The CJEU has also deemed information that would *"significantly impede effective competition (…), commercially sensitive information relating to the commercial strategies of the undertakings involved, their sales figures, market shares or customer relations"* as falling within the

[194] See the supplementary material, 20.
[195] See e.g., Case Case C-71/10 Communications v Information Commissioner, 28 July 2011, para.22 and Case C-234/22 Roheline Kogukond MTÜ and Others v Keskkonnaagentuur, 7 March 2024, para. 34.
[196] General Court, Case T-718/15 *PTC Therapeutics International Ltd v European Medicines Agency,* 5 February 2018, para. 84.
[197] General Court, Case T-377/18 *Intercept Pharma Ltd,* 18 June 2019, para. 54; Case T-189/14, Deza, a.s. v European Chemicals Agency, 13 January 2017, para. 56; Case T-545/11 RENV *Stichting Greenpeage Nederland and PAN Europe v Commission*, 21 November 2018, para. 101.

scope of the first indent of Article 4(2).[198] Information that is not in the public domain and gives the company an economic, strategic, or organisational advantage and that could be used profitably by other undertakings[199] or could allow a competitor to enter a specific market[200] would also be covered by commercial confidentiality. Such information could include methods of assessing manufacturing and distribution costs, production secrets and processes, supply sources, quantities produced and sold, market shares, customer and distributor lists, marketing plans, cost-price structure, sales policy, and information on the internal organisation of the undertaking.[201] **Therefore it is clear that the first indent of Article 4(2) of Regulation 1049/2001 was not designed to protect the reputational interests of companies or shield them from accountability towards the public for failures to comply with environmental law**.

While we acknowledge that sensitive commercial or industrial information that could be used by competitors to gain an advantage should not be disclosed, violations of EU law should not be covered by commercial secrecy. Given the content of the REF-9 project questionnaire, it is highly questionable that any sensitive business information was even present.

Moreover, shielding violations of the REACH Authorisation regime from public scrutiny creates a vastly uneven approach to breaches of EU law committed by companies while carrying out their commercial activities**. This essentially allows operators in violation of the REACH Authorisation regime to profit from their actions while other violations of EU law are exposed to the public**. For example, the Corporate Sustainability Due Diligence Directive[202] creates an open and transparent approach to enforcement of due diligence obligations, making it possible for the decisions of supervisory authorities imposing penalties on companies due to a failure to comply to be published and remain publicly available for at least three years.[203]

In this regard, **it is of particular concern that Germany informed ECHA of its intention to reconsider its participation in the Enforcement Forum should the Agency grant ClientEarth access to the requested documents.** This suggests a selective and protectionist approach to enforcement by Germany. If, in pursuit of defending this approach, a Member State would exit the ECHA Enforcement Forum, thereby compromising an important REACH objective – i.e. the harmonisation of enforcement actions – it raises legitimate doubts about the effectiveness of the enforcement practices and procedures in place. This is particularly concerning where the enforcement is aimed at protecting human health and the environment from the most harmful chemicals.

Furthermore, **France's refusal to grant access to documents via ECHA as it would risk exposing a company's identity is inconsistent with the policies applicable domestically in France**. As

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[198] CJEU, Case C-477/10 *Commission v Agrofert Holding*, 28 June 2012, para. 56, Case C-365/12 P, *EnBW*, 27 February 2014, para. 79, see also the General Court, Case T-44/17, *Camomilla Srl v European Union Intellectual Property Office*, 13 Nobember 2018, para. 43 and T-474/04 *Pergan Hilfsstoffe für industrielle Prozesse* v *Commission*, 12 October 2007, para. 65-66.

[199] General Court, Case T-198/03, *Bank Austria Creditanstalt* v *Commission*, 30 May 2006, para. 71, and Case T-474/04 *Pergan Hilfsstoffe für industrielle Prozesse* v *Commission*, T-474/04, 12 October 2007, para. 65.

[200] General Court, Case T-235/15 *Pari Pharma v EMA,* 5 February 2018, para. 108.

[201] General Court, Case T-441/17, *Arca Capital Bohemia v Commission,* 11 December 2018, para. 53.

[202] Directive (EU) 2024/1760 of the European Parliament and of the Council of 13 June 2024 on corporate sustainability due diligence and amending Directive (EU) 2019/1937 and Regulation (EU) 2023/2859

[203] "*The published decision should not contain any personal data in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council. The publication of the company's name should be allowed even if it contains the name of a natural person*." Recital 76 of the CDDD, see also Article 27(5) of the CDDD.

mentioned before, France has a publicly available online repository (*Géorisques*).[204] This repository includes information on inspection outcomes such as sanctions imposed. Thus, facilities operating in France reliant on a REACH authorisation fall within the scope of the repository and are publicly listed. Everyone can access the data of this repository free of charge. As the repository was set up relatively recently, it does not contain exhaustive information about past inspections. However, as a matter of policy, this means that documents like those requested are available to the public through this online resource.

No company should be allowed to benefit from violating the REACH authorisations. Information on such breaches should not be shielded behind commercial confidentiality. It is contrary to EU law and, in France's case, it is inconsistent with domestic practice.

4 Recommendations

Drawing from the results of the analyses, this Section makes various recommendations.

4.1 More relevant Article 117 reporting

The assessment in Section 3.3 finds that the whole rationale of the reporting under Article 117(1) is not fit for fulfilling the purpose of ensuring effective and timely administrative responses to violations of authorisation decisions. The sub-sections below provide recommendations to address this particular shortcoming. The Article 117(1) reports nevertheless have the potential to offer valuable insights for the Commission, the Forum and civil society, e.g. for identifying trends or understanding structural issues.

To unlock that potential, **the Commission should implement Article 117(1) so as to enhance clarity about the subject matter of reporting**. It should, in cooperation with the Forum, develop definitions for key concepts such as 'inspection' and 'control', vital to enabling a better understanding of the significance and the comparability of data submitted by different Member States. Implementing legislation or guidance could provide clarity. Likewise, the 2017 strategy document from the Forum, setting common criteria for conducting inspections of chemical regulations, lacks clear and precise definitions.[205] This recommendation reinforces the necessary 'Action' identified in the course of the 2018 review of REACH: "*ECHA's Forum and Member States are requested to establish comparable parameters on enforcement*".[206] Some work has already begun in that respect, e.g. in the context of a study commissioned by the Commission in 2015 to develop enforcement indicators for REACH and CLP.[207]

Second, **the Commission should simplify the Member States' tasks when it comes to providing the data required**. The reporting intervals are set at five years, while each time the scope of the report is, more or less significantly, adjusted. A key improvement would therefore be for the Commission to clearly instruct national authorities which data have to be reported *before* they conduct their enforcement activities.

[204] See https://www.georisques.gouv.fr/consulter-les-dossiers-thematiques/installations.
[205] ECHA (2017), Strategies and minimum criteria for enforcement of Chemical Regulations.
[206] COM(2018) 116, 9.
[207] PwC (2015), Study on "Development of enforcement indicators for REACH and CLP" - Final Report.

Third, **there is currently a very long break in-between the reporting moments**, a phase where lack of transparency creates uncertainties about the effective enforcement of REACH which can turn to distrust. **To increase timeliness and enhance the relevance of the report to inform the monitoring of enforcement activities, the reporting interval should be reduced.** From the Member States perspective, in administrative terms, they have to collect the data anyway so a shorter reporting interval, e.g. of one year, would arguably not create any additional burden. In fact, this was also foreseen as follow-up activity to the review of REACH in 2018,[208] and the Forum agreed in 2019 to pilot annual reporting on a voluntary basis,[209] yet the results of this exercise remain to be seen.

4.2 Call to industry action

Ultimately, the responsibility to ensure compliance lies with the companies manufacturing, importing or using SVHCs subject to authorisation. In this regard, structural compliance issues become apparent, and therefore **it should be for the industry associations, notably those active at EU level who know well chemical rules, to take leadership in their sectors and support companies in meeting their legal obligations**. Accountability of these activities has to be ensured, e.g. industry should report to authorities (e.g. the Forum) on the progress achieved, subject to agreed indicators.

4.3 Clear accountability framework

The Commission, the Member States and the Forum/ECHA should agree on a common approach, or Joint Action Plan (JAP)[210], adapting policies and administrative procedures on the enforcement of REACH Authorisation. The JAP should comprise the following elements:

To meet the requirements of Articles 125 and 126, **Member States need to ensure a level playing field of enforcement *within* their respective territories**, as the level of compliance and thus protection reached in a certain region must not be subject to 'competition' between varying administrative entities. This necessitates Competent Authorities willing and capable of steering the process, informed by closely timed reports of enforcement practice on the ground.

Authorities must adopt a fundamentally stricter and more pragmatic approach, moving away from an overly tolerant stance on non-compliance. The report indicates that the current lack of enforcement stems partly from a mindset that overly trusts the goodwill of companies, or avoids taking bold and dissuasive decisions due to concerns that companies may go to court. This fosters leniency from authorities toward non-compliant behaviors, to the extent that some companies may continue today to use SVHCs in complete illegality. While collaboration can be valuable when industry stakeholders are genuinely committed to compliance and seek regulatory support, it should not lead to systematic tolerance of non-compliance with regulations essential to public safety. Ultimately, the responsibility for understanding and adhering to the law rests with the industries that choose to operate in the chemical sector, and a proactive commitment to compliance, fueled by rigorous enforcement, must become the

[208] COM(2018) 116, 9.

[209] See All news - ECHA.

[210] Reminiscent of the JAP launched in response to the second REACH review, see ECHA and Commission (2019). At the time, this was triggered by the identified sky-high non-compliance with the registration rules. Several years after this review – which lacked enforcement data from authorisation – available evidence shows that non-compliance in the context of authorisation for SVHCs is just as unacceptable, calling for a just as resolute and concerted approach to ensure compliance.

standard. In concrete terms this means that **when inspections observe non-compliance, in most cases, this implies that the conditions to which the authorisation decision are subject to are not met (anymore)[211]. This should trigger mandatory disruption of activities related with the use of the Annex XIV substance at stake.**

Given the Commission's obligation to monitor granted authorisation decisions, Member States should report any detected violation against Authorisation rules on a rolling basis, i.e. by default within days.

The **Commission should commit to making appropriate use of the option to withdraw granted authorisations in the case of (severe) violations**. This would further incentivize compliance by industry while taking burden from enforcement agencies who may face difficulties in their hierarchies[212] would they intent to punish domestic companies. For the sake of transparency and predictability, the Commission should develop criteria pursuing as primary goal a high level of protection, how reported violations will be taken into account in the review activities under Article 61 REACH. It should also develop guiding criteria to ensure proportionality of direct withdrawals in reaction to detected violations. Before final adoption and publication, both sets of criteria should be discussed with Member States and stakeholders, including from civil society.

Further lessons should be learned as for the choice of the regulatory tools. In view of the overall lack of compliance and the enforcement challenges linked to the implementation of emission control measures at company level, the European Commission should always opt for the strictest regulatory option when considering how to significantly reduce the risk posed by most harmful substances. **Restrictions should be prioritised**. The granting of authorisations should be strictly limited to companies that have shown a clear commitment and concrete steps to substitution, and have systems in place to reduce emissions while working towards the phase-out.

The Forum should coordinate the harmonised implementation of the above recommendations, and should thrive to constantly improve the impact of enforcement work by increasing compliance levels in the context of Authorisation.

Specific commitments by industry associations to help stepping up compliance (see 6.2) could also be part of such a Joint Action Plan.

4.4 Changes to the REACH text

As the report has shown, much of the enforcement effort required to address the lack of compliance with the Authorisation regime could happen today, if only the various authorities, in the context of their own mandate and responsibilities, tightened the screw in their control and sanction of chemical operators.

However **changes to the REACH text, in line with the Chemicals Strategy for Sustainability's commitments to more rigorous ("*zero tolerance approach*") and better harmonized enforcement,[213] could also enhance this effort** by contributing to:

[211] See the standard clause used in authorisation decisions: "*The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report*".
[212] For example, where supervision of enforcement activities lies with ministries for the economy, or where historically this has been the case.
[213] COM(2020) 667, 17 et seq.

Accelerate the detection of non-compliance: National enforcement systems should be harmonized as much as possible to ensure that consistent criteria are applied to control operators involved in the production or use of Annex XIV chemicals. These criteria could be explicitly outlined within the REACH text. Additionally, establishing an EU-wide audit system within the REACH framework, modeled after the fisheries control mechanism, could empower the European Commission and ECHA to monitor, support, and, when necessary, intervene to enhance the enforcement of REACH, including its Authorisation regime, in alignment with their respective mandates. Should a Member State consistently fail to properly enforce REACH, the Commission must take steps to address this situation, including by initiating, in last resort, infringement proceedings. ClientEarth has provided a dedicated brief detailing what this audit system could look like.[214] REACH should moreover facilitate the submission of substantiated concerns over cases of non-compliance by third parties, including members of the public, so that authorities are alerted and can take action as early as possible.[215]

Enforce truly effective sanctions: activities involving the use of a banned SVHC can have serious effects on the environment and human health, starting with the health of workers. It is hence not acceptable that there are currently little incentives to comply. To remedy this situation, first and foremost, the sanction system must be harmonised and made sufficiently dissuasive. Some violations should attract mandatory and automatic sanctions in all Member States. Notably, companies must not be allowed to continue operating until the non-compliance has ended. ClientEarth has developed a set of recommendations to improve the sanction system under REACH.[216] It is also crucial that REACH explicitly requires the European Commission to withdraw an authorisation upon evidence of non-compliance by the holder of an authorisation – a corrective measure that is currently only implied within the existing text as shown in the above Section 2.2.

4.5 Ensuring greater transparency of enforcement actions and results

Transparency of enforcement of the REACH Authorisation regime must be increased on all levels. Contrary to the assertion of ECHA and certain Member States, transparency and public scrutiny would serve as an incentive to compliance and thus increase the effectiveness of the enforcement rather than undermining it. In this regard, we have several concrete recommendations:

Set up national registers of grave infringements, **as well as an EU registry**. These registers should include information on the inspections carried out, including any decisions on non-compliance, companies found in violation of the sanctions regime and imposed sanctions. That would make it possible to keep track of and analyse the effectiveness of the enforcement response. Both national and EU registers should be publicly available to ensure transparency and incentivise compliance. The French *Georisque* platform is a step in the right direction in terms of availability of information, which however needs improvement in relation to its usability.

ECHA should ensure transparency of non-compliance, or "name and shame", via public, and searchable, database of non-compliant companies. Transparency on non-compliant operators would create a supplementary incentive needed under REACH. As in other areas, for example, competition law, Corporate Due Diligence Directive or the EU Emissions Trading System, the names of companies in

[214] ClientEarth (2023), Demand #5: Give bite to REACH - sanctions and control.
[215] ClientEarth (2023), Demand #6 for REACH reform: Access to justice.
[216] ClientEarth (2023), Demand #5: Give bite to REACH - sanctions and control.

violation of REACH should be made public. Very recently, this concept has been incorporated in Article 25 of the Deforestation Regulation.[217]

[217] Regulation (EU) 2023/1115 on the making available on the Union market and the export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010.

hduguy@clientearth.org

jschenten@clientearth.org

www.clientearth.org