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10 years in: time for ECHA to disseminate strategic information to empower third parties

ClientEarth

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Contents

Executive summary

The European Chemicals Agency (ECHA) is a regulatory agency that makes decisions and provides scientific opinions on chemicals that companies want to manufacture, sell or use in the EU. Because of this role, ECHA holds a large amount of information on:

- The identity of chemicals, including their hazardous properties, the quantities in which they are manufactured, sold or used in the EU and how to handle them as safely as possible – indispensable to **make chemicals and their risks 'visible'**, in order to create awareness and make the right to choose a reality:

- The function of chemicals and in particular of harmful chemicals – indispensable to **have an informed debate on whether substances have societal benefits and whether safer alternative substances or technologies exist**;

- Compliant and non-compliant companies – indispensable for investors and consumers to **make informed choices and support enforcement authorities' efforts**;

- The rationale of the EU institutions' decisions related to ensuring chemical safety - indispensable to increase the **intelligibility of, trust in and accountability of their decisions**.

This report reviews the extent to which ECHA makes this information public, in compliance with its obligations set by EU law.

ECHA lists transparency among its core values[1], and, in the last years, has made important changes to better disseminate key information. However, there are still improvements to be made. Indeed, ECHA still falls short of complying with some of the obligations to disseminate information set by REACH,[2] the Aarhus Regulation[3] and Access to Document Regulation.[4] Considering it usually publish information only if prompted to, it fails to see that transparency has the capacity to help achieve REACH's objectives by allowing third parties - civil society, citizens, consumers, investors, and innovators (such as providers of alternative solutions) – to play an active role in its implementation.

This report analyses the progress and shortcomings of ECHA in achieving its transparency obligations in each of its core activities as defined by REACH: 'registration', 'evaluation', 'authorisation' and 'restriction' of chemicals, and proposes tailored solutions.

When it comes to the 'registration' of chemicals, ECHA has made progress. ECHA disseminates more information on its website and organises it in a more user-friendly way. However, some key information, indispensable for citizens to understand chemicals risks, is

* We would like to thank Martin Führ, Society for Institutional Analysis (sofia) at the Darmstadt University of Applied Sciences and Julian Schenten, Society for Institutional Analysis (sofia) ate the Darmstadt University of Applied Sciences for their valuable inputs.

[1] https://echa.europa.eu/about-us/who-we-are/values We are open and transparent in our actions and decision-making. We are easy to understand and to approach.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396 30.12.2006, p. 1)

[3] 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 (OJ L 264, 25.9.2006, p. 13–19).

[4] 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 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
(OJ L 145, 31.5.2001, p. 43–48).

still missing. For example, ECHA[5] still refuses to publish the quantity (tonnage bands) of chemicals manufactured/used per individual registrant. It also keeps confidential information detailing the scenarios anticipating how, where and to what extent humans and environment will be exposed to the chemicals registered. Information on the presence of substances of very high concern (SVHC) in articles remains insufficient, as well as on the control of registrations.

Considering the second pillar, ECHA publishes most of the final decisions related to its 'evaluation' activities. However, ECHA does not ensure transparency on which companies comply with their obligations under REACH, and which do not – hence creating an incentive to comply only when caught.

In the 'authorisation pillar', ECHA has improved its practice. More elements of the applications for authorisation are disclosed to inform the public consultation. However, key information is still redacted, preventing third parties from contributing meaningfully to the decision making process. In addition, ECHA needs to be transparent about the criteria it uses when evaluating the relevance of the contributions. It is not clear why some contributions, in particular those informing ECHA of the existence of alternatives, are discarded. In addition, when a SVHC is used following an authorisation, ECHA does not disclose systematically the quantities in which the substance is used, or the identity and location of the downstream users notifying ECHA. This is contrary to the Aarhus Regulation, the Access to Documents Regulation and the aim of REACH to substitute SVHCs with safer alternatives.

In the 'restriction' process, ECHA seems to treat third party contributions asking for softening the restriction more favourably than those calling for a stricter measure. ECHA needs to adopt a more transparent approach, clearly stating the criteria it uses to assess the relevance of third party contributions.

ECHA tends to improve transparency only when prompted to do so by third parties, and ultimately the EU Court. ECHA needs to become proactive and disseminate the information needed by third parties so that they can play an active role in the effective implementation of REACH.

[5] See ECHA Press Release dated 25 July 2012 https://echa.europa.eu/view-article/-/journal_content/81cace06-43bf-4756-aa10-784f3561ea4c; a decision taken after consultation with the Management Board "Advisory Group on Dissemination".

Introduction

In the 1990's the EU institutions and the Member States realised that chemical regulations failed to ensure health and environmental safety. The main issue was that the previous regulation did not solve the worrying 'data gap': very little was known about the hundred thousand chemicals[6] manufactured or used every day in the EU. **As a result, key actors were left in the dark**:

- Public authorities lacked the information needed to identify which substances require regulation because of the risks they pose to human health and the environment;
- The public had little information about the chemicals to which it is exposed, preventing individuals from making informed consumer, investment and political choices;
- Even chemical users tended to ignore the risks they created for their workers, the environment and the public.

It was indispensable to find a way to create and collect more information on chemicals. The EU institutions and the Member States imagined a solution which took the form of the Regulation **'REACH'** (for registration, evaluation, authorisation and restriction of chemicals), adopted in 2006. As stated in its Article 1(3), REACH places on 'manufacturers, importers and downstream users' the responsibility to use or place on the market substances 'that do not adversely affect human health or the environment.'[7] Part of this responsibility involves an obligation to gather information on the properties and impact of their substances, and to communicate it to the European Chemical Agency (ECHA). ECHA was specifically created to collect, manage, assess and disseminate this information.

Today, 10 years after REACH entered into force, the data gap has not disappeared, but it has started to shrink. Not all actors are left in the dark; the Member States and the EU institutions receive far more information on chemicals, and have effective legal tools to require missing information to be submitted. **However, some of the old issues remain**:

- Public authorities are still in the dark on many substances due to the fact that many companies do not comply with their obligation to provide information on their chemicals;
- The public remains generally ignorant of the chemicals to which it is exposed;
- Chemical users do not always receive appropriate information to control the risk;
- It remains difficult to know whether daily products contain chemicals, let alone in what quantity and the risks they pose, which may leave consumers, retailers, investors and recyclers in the dark.

In addition, some new issues have appeared, linked to the ways in which ECHA and the EU institutions interpret their own obligation to collect and share information:

- The information provided by industry is not systematically made public when it should;
- Some key decisions and enforcement activities under REACH are unduly kept completely or partially secret.

While recognising the progress brought by REACH and the efforts ECHA has made to improve transparency since its creation, this report takes stock of the key areas for which increased

[6] The Classification and labelling inventory includes over 130,000 entries while almost 17,000 substances have been registered under REACH
[7] Further underpinned by recitals 16, 18, 25, 29, 56, 58 („chain of responsibilities"), 86, 105.

transparency would yield significant results for the protection of human health and the environment.

It focuses in particular on the areas for which **transparency has the capacity to empower 'third parties'** (i.e. actors beyond public authorities and the companies constrained by REACH) **to support the implementation of REACH by:**

- Providing added **scrutiny** of the information provided by industry;
- **Contributing** to the decision-making process by providing key information;
- Making **informed choices,** the economic implications of which will create incentives to invest in safer alternative chemicals or technologies.

These 'third parties' include different actors. Civil society (e.g. environmental NGOs) has an important role to play in each of these actions as it has technical expertise, knowledge of the decision-making process and a capacity to inform and mobilise the public. Consumers are also key as they have the capacity to steer the market towards alternative solutions to dangerous chemicals, whether they are concerned with their health, the health of workers or the environment. Individual citizens also have the power to influence policies – local, national or regional - to protect their health and the environment, provided they have information on the chemicals they are exposed to. Investors have the power, with the right information, to push the companies they invest in towards safer alternatives or make informed choices in their investment. Finally, the companies that have invested in alternative solutions ('alternative providers' or 'innovators') hold key information that needs to be fed into the decision making process.

The need for active and systematic dissemination of environmental information has been recognised under EU law, following notably the ratification by the EU of the Aarhus Convention and the subsequent adoption of the Aarhus Regulation[8]. The Aarhus Convention hence states that the parties to the Convention, and thus the EU has recognised that:

> *'[…] every person has the right to live in an environment adequate to his or her health and well-being, and the duty, both individually and in association with others, to protect and improve the environment for the benefit of present and future generations,*
>
> *[…], to be able to assert this right and observe this duty, citizens must have access to information, be entitled to participate in decision-making and have access to justice in environmental matters, and acknowledging in this regard that citizens may need assistance in order to exercise their rights,*
>
> *[…], in the field of the environment, improved access to information and public participation in decision-making enhance the quality and the implementation of decisions, contribute to public awareness of environmental issues, give the public the opportunity to express its concerns and enable public authorities to take due account of such concerns,*
>
> *[…]the importance of the respective roles that individual citizens, non-governmental organizations and the private sector can play in environmental protection,'*[9]

[8] 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 (OJ L 264, 25.9.2006, p. 13–19)
[9] Aarhus Convention, available at: <http://www.unece.org/fileadmin/DAM/env/pp/documents/cep43e.pdf>, recitals 7 to 13 (extracts)

REACH itself, for example in its Article 119, creates legal mechanisms to ensure publication of key information. This is the reason why transparency is one of ECHA's five core values,[10] and why ECHA's management board has vowed in 2014 that the agency 'makes information available proactively'.[11]

However, a closer look at ECHA's functioning reveals that, while there has been some progress in recent years, the agency falls short of the requirements on transparency set by REACH itself, EU law and the Aarhus Convention. This endangers the ability of third parties – environmental NGOs, consumers, citizens, investors and alternative providers - to play their role in scrutinising the information provided, providing key information themselves, limiting their use of dangerous substances and pushing the market towards safer alternative solutions. This report assesses these shortcomings and proposes practical solutions.

REACH relies on four pillars: 'registration', 'evaluation', 'authorisation' and 'restriction' of chemicals. The first two pillars aim at collecting relevant information on chemicals and their potential risks to human health and the environment. Companies have to register information on the chemicals they want to place on the market; ECHA and the Member States evaluate this information as a 'follow-up'[12] and assess whether more is needed due to concerns raised. The last two pillars aim at taking measures to limit the presence or use of the substances identified as harmful and at incentivising the market to find safer alternatives.

Each of REACH's pillars contains provisions ensuring dissemination of information and giving ECHA an important role in their implementation. The Access to Document Regulation and the Aarhus Regulation also create dissemination obligation applicable to ECHA. The following sections analyse how well they are respected.

1 Registration

Registration is REACH's main tool to collect and generate information on the safety of chemicals. Article 5 of REACH summarises it in a nutshell: 'No data, no market'. Companies who want to manufacture or import chemicals in the EU, on their own, in mixtures or in articles, must provide information on those chemicals.

This process is supposed to create a 'passport' for the substance, identifying its name, characteristics, the conditions of its uses and its risks. The basic information collected is then supposed to be used to inform all other REACH processes (evaluation, authorisation, restriction). Its dissemination should empower third parties to scrutinise the information, contribute to decision-making and ultimately make informed consumption and investment choices. However, the first sub-section below will show that ECHA has interpreted REACH in a way that opposes the useful dissemination of crucial information gathered during registration. The second sub-section highlights a similar problem, this time concerning information on the presence of substances of very high concern in articles.

Finally, information collected through registration is frequently non-compliant with REACH. According to ECHA itself, a significant proportion of registration dossiers are not of a sufficient quality. ECHA points out that the main weaknesses include insufficient information on the uses of and exposure to substances and lack of robust risk management measures proposed for

[10] See https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency.
[11] See https://echa.europa.eu/documents/10162/13608/mb_61_2014_echa_transparency_en.pdf.
[12] REACH Recital 20.

each use.[13] The second sub-section will show that ECHA unduly withholds information on non-compliance.

1.1 Dissemination of registration information

REACH provides for the right of citizens to know about the properties of the chemicals they are exposed to in order to make informed decisions.[14] Article 77 gives ECHA the responsibility to make information publicly available over the Internet.

ECHA built early on a dissemination portal on its website[15], but it was of little use to understand hazards, risks and uses of chemicals. Key information, such as the identity of registrants was kept secret.[16] **Since 2012 however, the dissemination of information on chemicals from ECHA's portal has largely improved.** ECHA, recognised the importance of making available the data it holds, and started re-shaping its portal.

ECHA has made a number of improvements, such as:

- Publishing the names of the registrants of each substance and registration numbers;
- Publishing indicative information[17] on the quantities of the substances on the market;
- Organising the data on chemicals in 3 levels of complexity to serve different needs and audiences:[18]

  - 'Infocards' that provide a summary of the key information on a chemical;[19]

  - 'Brief profiles' that go deeper into the environmental, human health and physico-chemical properties of the chemical;[20]

  - 'Source data' that includes the specific scientific data submitted by industry to ECHA.

- Making it possible to search chemicals by regulatory activity (e.g. CLP,[21] SVHC identification, restrictions), hazard, country in which it was registered, uses and exposure, as well as presence in nanoform.

Despite these important improvements, ECHA's database is still missing crucial information that is necessary for the implementation of REACH as it was designed. Each missing category of information is explored further in the following sub-sections.

[13] REACH and CLP – the journey so far, ECHA-16-A-03-EN.
[14] See REACH, Recital 117 "EU-citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures".
[15] https://echa.europa.eu/information-on-chemicals/registered-substances
[16] EEB and ClientEarth, 2012. Identifying the bottlenecks in REACh implementation–the role of ECHA in REACh's failing implementation, page 20.
[17] ECHA adds up the tonnages of all the registrants of the same substance and then disseminates these figures on its website e.g. 1 000 000 - 10 000 000 tonnes per annum.
[18] See How to find information about chemicals at <https://echa.europa.eu/press/press-material/info-on-chemicals>
[19] See, for example, the info card for DEHP: https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.003.829
[20] See, for example, the brief profile for DEHP: https://www.echa.europa.eu/web/guest/brief-profile/-/briefprofile/100.003.829
[21] Under the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1)

1.1.1 Tonnage band information

Tonnage bands *per registrant* is essential information for all third parties – civil society, citizens, consumers, investors and alternative providers - because it is a proxy for risk. The higher the amount of chemicals that a company wants to place on the market the more information is required on the hazards and risks of the chemical. Article 12 associates specific obligations to tonnage thresholds (1 tonne, 10, 100 etc.). For example, carcinogenicity studies have to be performed only for substances registered over 1000 tonnes.[22] **Knowing the individual tonnage band is the key that unlocks knowledge of which obligations the industry has to comply with and that the EU and national authorities have to enforce.** It is the information civil society needs to scrutinize the decision-making process and ensure accountability, or that investors need to ensure they invest in compliant companies.

For hazardous substances, this information is even more important. Firstly, having data on the quantity, when read with information on where the substances are manufactured or imported, makes it possible to estimate the way and the extent to which humans and the environment are exposed to those chemicals in a particular area. Secondly, increased transparency on tonnage may create, through public, consumer or investor pressure, an incentive to decrease the presence of substances of very high concern (SVHC) in companies' portfolios and to develop safer alternatives. For example, investors could better evaluate the financial risk of the production of a single SVHC per producer. This could lead to divestment strategies targeted at companies involved in the manufacture or use of SVHCs.

Indicative information about the amount of chemicals a company registers can thus be a powerful tool to promote safer alternatives and empower citizens. This is exactly why Article 119 (2)(b) of REACH includes information related to the tonnage band within which a particular substance has been registered in the list of information to be made publicly available.

The problem stems from ECHA's decision to interpret this article in a restrictive way. ECHA decided that only **aggregated tonnage information** should be published. This means that if 10 registrants manufacture 10 tonnes of substance A, the only information published is that 100 tonnes of substance A were registered in the EU. However, **ECHA withholds information on the quantity manufactured by each registrant.**

This interpretation of Article 119(2)(b) is incorrect. This article does not refer explicitly to aggregated tonnage. It does refer to 'total tonnage band', but in the sense of the total tonnage band of each individual registrant. This is clear from the fact that it gives as an example of such 'tonnage bands' the exact bands referred to in Article 12, which deals with the threshold applicable to *individual registrants.* In addition, Article 119(2)(b) specifies that 'a party submitting the information' can ask ECHA to not disclose the information listed by Article 119 (provided it gives a justification accepted by ECHA). The information therefore has to be, in essence, of interest and be sensitive for the 'party submitting the information', i.e. the *individual* registrants. *Aggregated* tonnage band from all registrants of the same substance, cannot be of interest or sensitive commercially to an individual registrant. Only the **individual tonnage band could be.** ECHA's current interpretation of Article 119(2)(b) is therefore illogical.

REACH obliges ECHA to disclose total tonnage bands of each individual registrant, except if the registrant submits a valid confidentiality claim for the tonnage band in application with 10(a)(xi) – see subsection c).

[22] Article 12(1)(e), Annex X, point 8.9.1.

Improvement needed

ECHA needs to correct its wrongful interpretation of Article 119(2)(b) and make information on *individual* tonnage band public by default.

This would not prevent ECHA from maintaining confidentiality for specific cases, when requested by the applicant and duly justified in compliance with REACH.

1.1.2 Exposure scenarios

When they are compulsory, exposure scenarios are part of the Chemicals Safety Report (CSR). They describe the conditions in which people and the environment may come into contact with the registered substance. They include operational conditions that describe how the substance is manufactured or used throughout its life cycle. They also explain the risk management measures that the manufacturer uses to control exposure to humans and the environment or that it recommends downstream users apply for the same purpose.[23]

Under REACH, companies have to develop and include an 'exposure scenario' in their registration dossier when the substance has particularly dangerous properties. This is considered as being the case under REACH where a chemical meets the criteria for classification under certain hazard categories set out by the Regulation on classification and labelling of chemicals,[24] for example carcinogens, or if this chemical is found to be persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.[25]

Exposure scenarios are essential to understand the risks of the substances and how to manage them, as such when REACH requires to develop such a scenario, the company is also obliged to attach it to the Safety Data Sheet (SDS) – the document used to pass information along the supply chain.[26] REACH requires companies to provide SDS for hazardous substances as a tool to communicate the hazards and risks from specific uses of substances.[27]

REACH Article 119(2)(d) foresees that information held by ECHA that is contained in the safety data sheets should be published, unless claimed confidential by the registrants.

Exposure scenarios are part of the Safety Data Sheets and are indispensable to understand the risks deriving from the real-life use of a substance. They are therefore just as essential for anyone potentially exposed as for environmental NGOs. However, despite the importance of exposure scenarios, ECHA has decided not to make them fully public. In what seems to be an attempt to explain why they are not published, in its report on the operations of REACH and CLP, ECHA underlined that the exposure scenarios provided by registrants are generally of poor quality or not always communicated to the supply chain.[28]

[23] REACH, Article 3(37).
[24] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1)
[25] REACH, Article 14(4)
[26] REACH, Article 31(7)
[27] REACH, Article 31.
[28] Report on the Operation of REACH and CLP 2016, ECHA-16-R-08-EN, Page 77.

ECHA only publishes generic information on exposure scenarios and does not include the exposure estimates and the risk management measures that should be applied for each use. The information that ECHA presents as 'exposure scenarios' is therefore not worthy of the name, as it does not provide information on the risks of a specific use of a substance and how to manage such risks. In addition, very few dossiers contain any information on the exposure scenarios, which suggests that ECHA does not include the exposure scenario in the list of items to be checked in its completeness check procedures (see above para. 1.3).

It follows that ECHA is not in compliance with its obligation to publish exposure scenario information under Article 119(2)(d). Considering the importance of exposure scenarios, this situation is not acceptable. ECHA needs to systematically publish full exposure scenarios. Users in the supply chain, workers in particular, could then easily check the conditions for safe use. Finally, transparency could create an incentive for industry to improve the quality of exposure scenarios and better protect users of chemicals, which is deeply needed according to the issues reported by ECHA.

Improvement needed

ECHA needs to fully comply with the minimum requirements set by REACH for dissemination. Exposure scenarios are meant to document how people and the environment are exposed to harmful substances; hence both the public and the users of these substances must be able to have access to this information.

Low quality cannot be an excuse for ECHA to withhold this information from the public. Rather, transparency would increase the accountability for registrants failing to provide this information.

1.1.3 Justifications for confidentiality claims

Article 119 of REACH lists the minimum information that must be made publicly accessible over the internet and free of charge. Information listed under Article 119(1), such as the name of the substance or the results of toxicological studies, cannot be withheld from the public. However, Article 119(2) of REACH gives registrants the opportunity to claim that certain data from their registration dossier should remain confidential. A registrant can claim confidentiality for the degree of purity of the substance, the tonnage band of registration, study summaries or robust study summaries, information that is listed in a safety data sheet, etc.

While it is important to preserve the right to protect confidential data given to registrants by REACH, **such claims should be limited to situations where there is a specific, actual, legitimate and evidenced need for secrecy in accordance with the jurisprudence of the Court of Justice of the EU**.[29] Also, a user of ECHA's portal should be able to understand why certain fields are marked as confidential – the reason why confidentiality was claimed, and granted, has to be made public.

ECHA has the obligation to check the existence and adequacy of the justifications provided in confidentiality claims.[30] To this end, ECHA developed a data submission manual for claiming

[29] See Court of Justice, case C-39/05P, Sweden v. Council, ECR 2008, p.I-4723, paragraph 36: "In view of the objectives pursued by Regulation 1049/2001, [the] exceptions must be interpreted and applied strictly." This interpretation rule is also laid down in Article 4(4), last subparagraph of the Aarhus Convention and in Regulation 1367/2006, Article 6(1).
[30] Article 119(2).

the confidentiality of data in IUCLID, the platform used to upload the information needed for registration.[31] ECHA reported that it accepted 85% of all confidentiality claims showing a low-level of scrutiny of industry's demands.[32] However, **ECHA has not made public the reason why it accepted the confidentiality claims even though those decisions resulted in withholding information that the legislator deemed important to disseminate**. Without full transparency on the process used by ECHA to examine confidentiality claims and on the rationale of its final decisions, no scrutiny on the confidentiality claims process is possible.

Currently, when ECHA accepts a confidentiality claim, it marks the field concerned in its database as '*confidential'* without any explanation or reference to a decision making process. For example, ECHA's database contains 1048 substances for which at least one confidentiality claim of the registrant was deemed justified by ECHA, while a search based on confidentiality of the tonnage yields 4,757 results.[33] In addition, the database returns 800 results on the confidentiality of whether or not the Chemical Safety Assessment (CSA) was performed.[34] The CSA includes the basic information on the hazardous properties of the substance and an estimation of its exposure. It is extremely difficult to understand or justify why the existence of a safety assessment of a substance would be confidential.

Improvement needed

In order to increase the confidence of the public, the confidentiality claims process has to be transparent. ECHA should include information on:
- The reasons why the information was claimed to be confidential (e.g. protection of intellectual property, information can reveal manufacturing process);
- The reasons why the disclosure of such information would actually and seriously harm the commercial interest of a company (e.g. in the case of IUPAC name, or name of a company);
- The legal basis for claiming confidentiality and the related ECHA decision that accepted the confidentiality claim, to allow challenges to such decisions.

EU law on access to documents does provide for exceptions to the principle of full access, but each exception has to be specifically justified by evidence demonstrating that disclosure would actually and seriously harm the interest being protected.

1.2 Notifications of substances of very high concern in articles

REACH has introduced obligations and mechanisms for companies to identify and document the presence of the substances contained in articles produced or imported in the EU, as well as the conditions for safe use. This information is important because it:

- Enables the safe use of chemicals present in consumer goods, by giving clear indication on how to use the product and allowing consumers to choose the risk they are exposed to;
- Facilitates substitution, by clarifying the scope of articles for which an alternative is needed;

[31] Dissemination and Confidentiality under REACH Regulation, ECHA, April 2016.
[32] ECHA, Report on the Operation of REACH and CLP 2016, Page 54.
[33] Search performed on 11 October 2017.
[34] Search performed on 11 October 2017.

- Supports the transition towards a circular economy, by allowing recyclers to understand the potential risks of recyclates containing SVHCs.

In their registration dossiers, registrants must describe the uses of the registered substance in articles. This information is particularly crucial when the substance is identified as of very high concern (e.g. mutagenic, carcinogenic, etc.).[35] This is why, in addition to the registration obligations, Article 7 of REACH requires producers and importers of articles (products) to notify ECHA when their articles contain substances of very high concern (SVHCs) if two conditions are fulfilled:

- The SVHC is present over a concentration of 0.1% weight by weight; and,
- The total quantity of an SVHC is higher than 1 tonne per year per manufacturer.

The producers and importers have to provide information about themselves and the substance, and a description of the uses of the substance in the articles as well as of the use of the articles.

This information complements, and therefore must be read in conjunction with, the information registrants have to provide in their registration dossiers; where registrants must **describe the uses of the registered** substance in articles. When the substance is classified as dangerous or is a PBT/vPvB, those uses have to be covered by **a safety assessment**.

Concerning this information in registration dossiers, ECHA stated, 'the amount and adequacy of information in registration dossiers for the safe use of substances in articles is still very limited'.[36]

In addition, by the end of 2015, ECHA received 359 notifications of the presence of SVHCs in articles for a total of 38 SVHCs.[37] As ECHA noted, the low figure is likely to illustrate a low level of compliance.[38] However, it is **not clear what ECHA has done to ensure better compliance of companies with their obligations**.

ECHA has also not fully disclosed the information it did receive in the few notifications sent by companies. ECHA disseminates this information in a **very generic** way, simply listing broad categories of articles, for example 'decoration articles' in which the substances may be found.[39] No information is given about the exact product in which the article is contained and what company has notified it, or about the expected concentration in the article. This type of broad information does not allow achieving the objective of Article 7, which aims at linking SVHC to specific goods.

Such precise information could be used by consumers to favour companies consciously phasing out dangerous chemicals in favour of better alternatives, but ECHA prevents the creation of such incentive by disseminating the information in an unusable format. It could also be used by investors to help them choose SVHC-free investments and push the market towards SVHC-free alternative chemicals or technologies. Finally, this information is crucial for civil society to hold companies accountable in case of breach of their duties.

[35] Fulfilling the criteria set out in Article 57.
[36] Report on the Operation of REACH and CLP 2016, ECHA-16-R-08-EN, Page 120.
[37] Ibid.
[38] Ibid.
[39] Information on Candidate List substances in articles https://www.echa.europa.eu/web/guest/information-on-chemicals/candidate-list-substances-in-articles-table; see for example https://echa.europa.eu/documents/10162/19421f25-94fe-4a1c-8618-6578e31e7a93.

Improvement needed

In order to improve industry compliance, and empower consumers, investors and recyclers to make informed choices, ECHA should share more precise information on substances in articles on its website, including the names of the companies providing such information.

1.3 Completeness checks

As the gatekeeper of the registration process, after receipt of the registration dossier, ECHA simply has to carry out a 'completeness check',[40] i.e. verify that all the information listed under Articles 10[41] and 12[42] 'have been provided'. If the registration dossier is not complete **ECHA cannot legally grant the registrant a registration number**.[43] ECHA could use this power to create an incentive for the industry to provide accurate and complete information: without the registration number, chemical manufacturers and importers cannot place a substance on the market. This is the primary objective of REACH, which is expressed in Article 5: 'no data, no market'.

Unfortunately, ECHA largely ignored its obligation to carry out a thorough check of the completeness of the registration dossiers. ECHA interpreted its role by creating a 'check process' that could be automatically managed through software – a process called the 'Technical Completeness Check'. This approach was flawed in two ways. Firstly, it showed that ECHA holds to an overly restrictive and formal interpretation of its role. Article 20(2) REACH does say that the completeness check does not include an assessment of the quality or the adequacy of any data and justifications submitted. However, when interpreted in light of the goal of registration, it does require ECHA to control that the data provided is at least understandable and usable as it is supposed to be the basis on which the other pillars of REACH (evaluation, authorisation, and restriction) rely. Secondly, the Technical Completeness Check did not work in practice. This software only checked the *presence* of an alphanumerical value in the different cells of the registration dossiers. The software could not verify whether the information included had any meaning. For example, if ECHA's software had to examine a cell where a company had entered 'asdf4fnsj kfns3djfkn' it would have considered the entry valid. The system therefore almost created an *incentive to cheat*, reinforced by the fact that ECHA provided the registrants with a tool to check in advance whether the dossier would pass the completeness check. For those who intended to cheat the system this was very convenient. They were able to add meaningless accumulations of characters until the completeness check plug-in indicated a green light.

The result was that the basic tenet of REACH, no data no market, became meaningless.[44] The inadequacy of the process did not go unnoticed; it was criticised by ECHA's Management Board, by Member States and by NGOs.[45] ECHA nevertheless maintained the same system

[40] Article 20(2).
[41] Article 10 lists the information to be submitted for general registration purposes.
[42] Article 12 refers to the information to be submitted depending on tonnage.
[43] ibid.
[44] REACH, Article 5; Recital 19 of REACH explains this mechanism: 'the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency. Registered substances should be allowed to circulate on the internal market.'
[45] EEB and ClientEarth, 2012. Identifying the bottlenecks in REACh implementation–the role of EChA in REACh's failing implementation, pages 11-13.

for years. Since 2010, the issue has been discussed several times by the Management Board.[46] The European Parliament's Environment Committee also encouraged ECHA to start implementing REACH's primary principle, 'no data, no market' affirming that "compliance is not and cannot be voluntary: merely 'promoting' stakeholder understanding, 'stimulating' the preparation of high quality dossiers, and 'encouraging' the updating of dossiers is not satisfactory. […] Moreover, the completeness check should not be limited to a simple mechanic check of whether all the boxes and sub-boxes required have been filled out irrespective of content." [47]

Unfortunately, nothing could shake ECHA from implementing its flawed policy. **It is only in 2016**, **when the Board of Appeal considered this practice as being a breach of ECHA's obligation, that it accepted the need for change**.[48] ECHA's justification for ignoring its duty to thoroughly check that registrants provided information was "that the use of an automated system for the completeness check is a 'practical necessity' and helps to ensure the efficient processing of registrations".[49] Following the decision, ECHA announced that it would re-examine all decisions granting a registration number to check that the dossiers are actually complete, including manual verification, when needed.[50]

After having been found in breach of its obligation for so long, it would have been logical for ECHA to ensure full transparency on the actions it has adopted to correct the situation. This is not the path chosen by ECHA; **the review process is submerged once again in secrecy**. Despite the fact that ECHA may have granted thousands of unlawful registrations because of its failure to create an efficient completeness check, **ECHA refuses to disclose which registrations are affected.** This is not a formal issue: all substances registered illegally since 2008 may have been used in ways that may harm health and the environment. If ECHA maintains secrecy, the public and civil society, consumers and investors, will never know which ones.

Moreover ECHA is still **secretive about many aspects of how it grants registration numbers**. The following information is still withheld**:**

- What criteria are used to select dossiers for manual completeness check;
- What information is being checked by the completeness check procedure;
- Whether the Chemicals Safety Report is going to be thoroughly checked for all the mandated information;[51]
- What circumstances would trigger a revocation of a registration number;
- Whether a registration number has been revoked and the names of the registrants concerned.

[46] See e.g. Minutes of the 27th meeting of the Management Board 27-28 September 2012, MB/M/03/2012 final and Minutes of the 28th meeting of the Management Board 13-14 December 2012, MB/M/04/2012 final.
[47] Letter by the chair of the European Parliament's ENVI Committee, Mathis Groote to ECHA's Executive Director from May 2012,IPOL-COM-ENVI D (2012) 26338.
[48] Case A-022-2013, 15 March 2016. In particular paragraph 99 "The Agency argues that, when performing the completeness check under Article 20(2), it is not obliged to verify the quality or the adequacy of any data or justifications submitted. As the Intervener inserted text into all the necessary fields in its registration dossier and provided a chemical safety report, its registration was considered to be complete. The Agency adds that the completeness check process is fully automated from the point of receipt of the registration dossier to the issuing of the decision. The IT system used for performing completeness checks is not designed to verify whether the text inserted by registrants in their registration dossiers is meaningful but merely if information exists.
[49] Case A-022-2013, 15 March 2016. Paragraph 106.
[50] ECHA/NA/16/14, ECHA to review completeness of registrations.
[51] Although included in Article 10, ECHA did not check that the Chemicals Safety Report included all required fields but only that an attachment to the registration dossier existed.

So far ECHA has only published statistical data on the new completeness check, which does not provide any guidance on which substances have been on the market illegally, nor where and for what uses.

Improvement needed

To ensure the accountability of companies allowed to place substances on the market, ECHA should disseminate all the details on the completeness check, including all the substances and registrants that failed the "real" completeness check.

In addition, ECHA should clarify what is included in the scope of their completeness check, the selection criteria and the consequences of failing the completeness check, including data on past decisions.

2 Evaluation

The second pillar of REACH deals with the evaluation of the data that has been submitted by the chemical industry. It includes three processes:

- The **examination of testing proposals**,[52] a tool for minimizing animal tests and ensuring that only necessary tests are carried out;[53]

- The **compliance check** of registrations,[54] (also called **dossier evaluation**), where ECHA can verify that the information submitted by the companies complies with REACH requirements and that the risks deriving from the use of these substances are adequately managed. This is a different step to the 'completeness check' described in section 2.1.2; it requires a broader and deeper qualitative analysis. According to REACH, ECHA must check for compliance of at least 5% of the registration dossiers for each tonnage band.[55] ECHA publishes a list of substances that may be subject to compliance check. This list is developed in accordance with ECHA's regulatory strategy[56] and it is based on the results of the common screening approach[57] that has been developed by ECHA together with the Member States.

- **Substance evaluation** aims at investigating whether the use of a substance may pose risks to human health or the environment[58] (where the data collected through registration and other available data indicate "initial concerns" [59] but are is not sufficient to determine if a risk exists). The assessment is carried out by a Member State, while the final decision on further required from the company(ies) that registered the

[52] To minimize tests on vertebrate animals REACH provides for registrants to request to ECHA to carry out a test.
[53] REACH, Article 40.
[54] REACH, Article 41; different to the completeness check under Article 20(2) referred to in Section 2.1.2.
[55] REACH, Article 41(5)
[56] ECHA 2014, Safer chemicals - focusing on what matters most. A new strategy for compliance check to improve the quality of information provided by companies, https://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf (26.5.2017).
[57] The Common Screening Approach for REACH and CLP Processes covers the identification and investigation of substance (and dossier) specific information to make a preliminary assessment on whether that substance (or dossier) should be handled via a particular REACH or CLP process (i.e. Classification and Labeling, or compliance check, or substance evaluation, authorisation or restriction). ECHA 2015, A Common Screening Approach for REACH and CLP Processes, https://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf/ (17.11.2017).
[58] REACH, Recital 20, Chapter 2 of Title VI.
[59] See https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan.

substance is adopted by ECHA. Substances undergoing this process are listed in the community rolling action programme (CoRAP) which is updated every year.

For all these processes ECHA adopts decisions through the Member States Committee.[60] ECHA publishes a progress report on its activities under 'Evaluation' every year before the end of February, but generally carries out these processes with a high degree of secrecy that hampers meaningful contributions by civil society (section 2.1). This secrecy extends to what happens after one of ECHA's decisions has been appealed before ECHA's Board of Appeal[61] (section 2.2).

2.1 Status and outcomes of dossier evaluation

ECHA is obliged to carry out compliance checks for only 5% of registration dossiers, which is a very small percentage. It is therefore crucial that ECHA relies on other tools to encourage companies to comply with their obligations. However, even though ECHA has continuously reported that the level of compliance remains low, it has not used what could be a very efficient incentive to comply: full transparency on non-compliant companies.

One of the main problems in the implementation of REACH has been the widespread lack of compliance in the registration of chemicals. ECHA highlighted, for example, that for about 3000 substances, the properties of the registered substances are unknown.[62] ECHA made timid steps to increase the transparency of the process, first by publishing a list of substances potentially subject to compliance checks and then by regularly updating this list since 2015.

ECHA committed to enhance dissemination of available dossier evaluation information by the end of 2016,[63] which led to certain improvements in the online inventory[64] of dossier evaluation decisions. In particular, ECHA now links the information on each substance to any compliance check decision.

Yet, despite plans to disseminate information about on-going procedures (e.g. status within the compliance check process) this information is still not available, including a general overview of all substances subject to a compliance check. Considering how low the level of compliance is, transparency would increase the scrutiny of civil society and increase pressure on national enforcement agencies to act on incompliant registrations.

In addition, it is common practice for ECHA to interrupt a compliance check after having drafted a decision if the registrant in the meantime decides to comply by updating their registration dossier. ECHA reported that 247 out of 1536 compliance checks carried out between 2009 and 2015 were terminated after a draft decision was sent, upon update by the registrant.[65] This means that for roughly one out of six compliance check procedures, there is no public knowledge and those draft decisions remain secret. Despite appreciating the good will of companies putting themselves in compliance after receiving a draft decision, such secrecy is an incentive for registrants to act only after 'getting caught'.

[60] Committee composed of representative of each Member State (Article 85(3)).
[61] The Board of Appeal is responsible for deciding on appeals lodged against certain decisions of the Agency taken under the REACH Regulation and the Biocidal Products Regulation. Although the Board of Appeal is part of ECHA, it takes its decisions independently.
[62] See ECHA-17-R-10-EN. Workshop on the implementation of ECHA's integrated regulatory strategy – proceedings, May 2017, pages 11-12.
[63] ECHA 2015, Workshop on Implementing the Compliance Check Strategy - Proceedings. doi: 10.2823/695560, https://echa.europa.eu/documents/10162/13628/cch_workshop_2015_en.pdf (26.5.2017), p. 13.
[64] See https://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions (26.5.2017).
[65] Report on the Operation of REACH and CLP 2016 Reference: ECHA-16-R-08-EN, Figure 20, page 59.

Further, **even when companies receive a final compliance check decision, ECHA keeps on defending the anonymity of the companies** that have decided not to comply with REACH by refraining from publishing the names of these companies. Despite the REACH text affirming that non-compliance with the regulation 'can result in damage to human health and the environment',[66] the companies responsible for such potential damages are protected from public scrutiny.

The last step of the procedure is also undisclosed. Compliance check decisions set deadlines by which companies have to remedy their non-compliance. If a company does not comply by the deadline, ECHA sends a 'statement of non-compliance' to the relevant Member State with a copy to the registrant.[67] **These 'statements' are not disclosed to the public**.[68] Such an approach makes it impossible for civil society to support the enforcement of REACH and to spur action of enforcement authorities on specific cases of non-compliance. This information would also be helpful for investors to make informed choices.

This practice threatens REACH's reputation as the most ambitious chemical regulation in the world. It also impacts the reputation of all the companies involved as it creates a suspicion of non-compliance for all of them when only the companies identified as non-compliant should be singled out. It lowers the level playing field and allows unfair competition by non-compliant companies. By pursuing this culture of secrecy, ECHA creates an obstacle to the accountability of part of the chemical industry.

Improvement needed

The secrecy maintained by ECHA over non-compliance is an incentive for non-compliance and misses an opportunity to single out virtuous companies.

To make non-compliant companies accountable, ECHA should make public **every** situation where a company is found to be non-compliant.

If a company corrects the situation right away, the information should also be made public, which will evidence the company's good will.

If a company does not correct the situation, this information should also be made public, in particular when a 'statement of non-compliance' is adopted.

2.2 Follow-up to Board of Appeal's decisions

ECHA's Board of Appeal is responsible for deciding on appeals lodged against certain decisions of the Agency, notably under REACH. Although the Board of Appeal is part of the Agency, it takes decisions independently. Under REACH, the Board of Appeal can review, among others, ECHA's decisions to grant a registration number (following the Article 20 'completeness check'); data sharing dispute decisions, 'compliance check' decisions and

[66] REACH, recital 122.
[67] ECHA 2017, Follow up to dossier evaluation decisions, doi: 10.2823/892258, https://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf (26.5.2017).
[68] Rather statistical data in this respect is presented at ECHA 2017, Evaluation under REACH: progress report 2016, doi: 10.2823/588707, https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf (26.5.2017).

substance evaluation decisions. Most cases submitted to the Board of Appeal relate to the Evaluation chapter of REACH.

When the Board of Appeal takes a decision, it may either reject the appeal that was brought or uphold it and annul ECHA's decision in part or in its entirety. As evaluation decisions take up a considerable amount of ECHA's resources, it is even more crucial that ECHA follows up on the decisions of the Board of Appeal. The reason for annulling a decision may be procedural in nature. For example, ECHA may not justify its request for information adequately[69] or such request may lack clarity.[70] In that case, ECHA should renew its request following the appeal, and remedy the procedural flaws identified.

However, with the notable exception of the decision that mandated ECHA to recheck the completeness of registered substances (see above 2.1.1), there is **no information available on what steps ECHA has taken to follow up on the Board's decisions**. In general, ECHA seems to abandon the action it has initially planned, even if it was not struck down on substantive grounds and is therefore fully justified.

Improvement needed

ECHA dedicates much of its resources to the Evaluation processes. Companies try to challenge ECHA's decisions before the Board of Appeal, and sometimes win their case.

This is, however, not a reason for ECHA to systematically give up on their initial decisions. When an appeal has been upheld on procedural or formal (as opposed to substantive) grounds, ECHA needs to review the decisions, correcting the errors identified by the Board of Appeal.
If not, the resources used for its decisions are wasted.

3 Authorisation

The Authorisation process is central in the REACH system: it aims at phasing out substances that the EU has targeted because they are of very high concern, and at promoting their substitution with safer alternatives.[71] The authorisation process consists of three steps. Firstly, substances identified as of very high concern are placed on the 'candidate list', then in a second step, on the 'authorisation list'. Once a substance is on the latter, companies interested in it will have to apply for a permit limited to a specific use, called 'authorisation'. Authorisations, adopted by the Commission following the opinion of ECHA committees and a public consultation, detail the conditions under which the SVHC can be legally used. The following sections, detailing the areas in which actions are needed, concern this third step. Transparency in this process is crucial to allow for meaningful participation from all relevant third parties,

[69] See, decision A-005-2014 Akzo Nobel and Others where the Board of Appeal found that ECHA didn't justify requesting information that was standard for one registrant from all the Appellants under the substance evaluation procedure.
[70] See decisions A-008-2015 Evonik Degussa GmbH; A-009-2015 Iqesil Sa; A-010-2015 Rhodia Opérations Sas; A-011-2015 J.M. Huber Finland Oy where the Board of Appeal found that the Contested Decision breached the principle of legal certainty because it did not clearly define the terms 'forms' and 'grades' of nanomaterials.
[71] Article 55

including civil society defending the public interest and companies offering safer alternative substances or technologies.

3.1 Third party consultations

The authorisation process aims at the replacement of SVHCs with safer alternative substances or technologies. When a company applies for an authorisation under Article 60, it has to provide data, including a risk assessment, an analysis of alternatives for the substance concerned as well as a socioeconomic assessment.

Article 64 of REACH requires ECHA to carry out a public consultation for each application for authorisation received. For ECHA and the Commission, this is an opportunity to get information on alternatives from other sources than the company who wants to keep using or keep supplying a substance of very high concern; for example from civil society, alternative providers or downstream users. It is also an opportunity for stakeholders defending the public interest to scrutinise the information provided by the applicant under the risk assessment or the analysis of the availability of alternatives. However, several barriers exist to the meaningful contribution of third parties.

3.1.1 The information disclosed to third parties before the consultation

There has been an improvement in the information provided online to support the public consultation. At the beginning of the implementation of the authorisation process, ECHA would only publish non-confidential summaries of key documents (Chemical Safety Report, Analysis of Alternatives, Socio-Economic Analysis).[72] After civil society requested access to applications for authorisation in 2013, ECHA started to request from applicants that they provide identical documentation for the Committees and the public, with the possibility to redact in the document the confidential information. This access to document request resulted in a legal challenge brought by an applicant for authorisation, won by ECHA in early 2017.[73] This approach provides better clarity on what information is withheld from the public and can be challenged on a case-by-case basis.

However, when requested to disclose some of the information redacted, ECHA still refuses to disclose key information such as:

- The tonnage corresponding to the anticipated quantities to be used (unless disclosed in the first place by the applicant); indispensable to understand the extent to which the substance of very high concern is expected to be released into the environment and thus falling into the category of information on ‘emissions into the environment’ under the Aarhus Regulation; and,
- Information that would be fundamental for alternative providers to provide useful input in the public consultation, e.g. the required performance of the substance or technology according to the demand-side of the market.

[72] See for example AfA 0001-01 https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/1601/term
[73] Judgment of the General Court (Fourth Chamber) of 13 January 2017 Deza, a.s. v European Chemicals Agency.Deza v ECHA, ECLI:EU:T:2017:4

3.1.2 The justification for discarding information from third parties

Third parties are given opportunities to contribute in the authorisation process. First, during the public consultation and then, if their contribution on alternatives are considered relevant, during 'trialogues', meetings created by ECHA in which they can discuss their information with ECHA and the applicant. The problem is that it is not clear what evidence third parties would need to provide in the public consultation to call into question the applicant's claim that no alternatives are suitable.

ECHA's Socio-Economic Analysis Committee (SEAC) is the body responsible for assessing the technical and economic feasibility of alternatives. SEAC tends to dismiss contributions from third parties stating that alternatives are available with little justification or no justification, whereas the applicant's statements dismissing the existence and/or feasibility of alternatives seem to be accepted with little scrutiny.[74]

In addition, the trialogues are not used to their full potential. These meetings tend to turn into an exercise of word against word, playing in favour of the applicant, when they could be used to do a critical assessment of the information on alternatives provided by the applicant in light of the contributions from third parties.

Improvement needed

ClientEarth welcomes the improvement made in the information disclosed to third parties before the consultation. However, additional improvements are needed to ensure that third parties can contribute meaningfully:
- ECHA should publish key information submitted in applications for authorisation, such as tonnage used, and information on the required performance of the substance.
- ECHA should create a clear methodology to test the existence and feasibility of alternatives so that alternative providers know what information they should submit.

This would help third parties, and in particular alternative providers, to contribute meaningfully to the process. Without this input, the objective of the authorisation process – to promote the replacement of SVHCs with safer alternative substances or technologies – is significantly hampered.

3.2 Downstream Users Notifications

Under REACH, downstream users working in the supply chain of authorisation holders can use a SVHC without going through the same procedure, provided that they respect the conditions of the authorisation.[75] When using an authorisation, the downstream users must send a notification to ECHA. The objective of the notification is for public authorities to have a

[74] See for example Opinion on an Application for Authorisation for Lead chromate sulfochromate yellow (C.I. Pigment Yellow 34) use: Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking, page 15: "SEAC tends to agree with the applicant that from the perspective of technical feasibility, no suitable alternatives are available. However, based on the conflicting comments received, SEAC concludes that this issue needs further consideration […]". See also Opinion on an Application for Authorisation for Chromium trioxide use: Functional chrome plating at page 24 it is stated that "the lack of a thorough assessment on economic feasibility makes it impossible for SEAC to conclude on this aspect" however, despite third party submissions claiming that feasible alternatives exist, SEAC recommended that authorization is granted.
[75] REACH, Article 56(2).

full picture of who uses SVHCs, where, why, in which quantities and with what risks. The notification must include any information needed by enforcement authorities to assess whether the conditions of the authorisation are met. In order to be usable, notifications therefore need to include, *a minima*, the authorization number, the name and location of the facility, the quantity of the substance used, the number of people exposed, a description of the use, and any other information required by the authorisation. This information is needed in order to obtain a full picture of the population directly and indirectly exposed and thus the magnitude of the risk associated with the use of the substance of very high concern. It is therefore indispensable for the enforcement authorities. It would also be important to describe any involvement in substitution activities.

ECHA decided to publish some information on the process, but this was too general to be useful. ECHA only publishes statistics regarding the number of downstream companies covered by an authorisation.[76]

In November 2016, ClientEarth requested access to the register of downstream users who have submitted a notification to ECHA. In its initial reply, ECHA accepted to give access to the **names** of the downstream users and the **precise location** of the facility where the substances of very high concern are used **unless there was only one authorisation holder**. In this case, ECHA refused to give access either to the identity of the company or the precise location of their sites. It also **initially refused to give access, for any notification, to information on the quantities used by each downstream user**. Following ClientEarth's confirmatory request, ECHA provided tonnage per downstream users when companies agreed to disclose, except for one substance. In that case ECHA provided an aggregated tonnage only. It also does not systematically disclose the names of downstream users and the location of their sites. This raises two issues:

Firstly, ECHA has adopted a **default position of non-disclosure** until it is prompted by a specific request, and in some cases forced by the EU Court. An adequate implementation of REACH, and the Aarhus Convention, in light of the principles of good governance with which the EU aspires to comply, requires a proactive attitude when it comes to publication of information related to dangerous substances emitted into the environment. ECHA, as a public authority, serving the public interest as opposed to the private interest of the chemical industry, should therefore disseminate this information on its own initiative. The information disclosed at ClientEarth's request should be proactively disseminated.

Secondly, the **justifications** given by ECHA for its decision not to fully disclose the information are **inadequate**.

In order to justify its decision to keep confidential the information on downstream users in cases where only one authorisation holder exists, ECHA affirmed that disclosing this information would reveal the links between the authorisation holder and the downstream user which would undermine the protection of commercial interests. To refuse the disclosure of this information ECHA relies on the provisions of Article 118 of REACH stating that revealing the link between a manufacturer or importer and its distributors or downstream users 'shall normally be deemed to undermine the protection of' the commercial interest of the company.

However, when it comes to SVHCs, the goal of REACH to promote the substitution of these substances should prevail over the interest of the supplier of the substance to maintain its

[76] https://echa.europa.eu/du-66-notifications

market. Since the only competition that the sole holder of an authorisation may have is a provider of a safer alternative, such commercial protection should not be granted.

In addition, the quantity of the SVHC used is another important piece of information that ECHA refuses to disclose systematically, even though it is indispensable for the public to know how much is being handled in a specific location, by a specific company, in order to be placed on the market or used on site. ECHA justifies its position using Article 118 of REACH which lists information 'that shall normally be deemed to undermine the commercial interests of the concerned person', and hence not disclosed.

However, ECHA adopts a wrong interpretation of this provision when it affirms that it covers information on tonnage **for substances of very high concern, in the context of the authorisation procedure**. The wording of Article 118 clearly indicates that only information on tonnage submitted **in the context of the registration** is covered. Indeed, it refers to the precise tonnage of the substance or preparation manufactured or placed on the market as harmful for the commercial interest of a company. In the context of the authorisation procedure, information on tonnage is by nature different from the information on quantities manufactured, or placed on the market. It is information about extremely harmful substances that are to be used under the specific conditions set in the authorisation.

In addition, this information is essential for people living in the area where the substances are being used. One major source of exposure from chemicals is via the environment, and an estimation of the magnitude of such exposure would be impossible without knowing the precise quantity that the company is using. As an example, the following calculation was made by the RAC:

> *"Based on the use of 32,000 metric tonnes HBCDD (8,000 t/a during four years from 2015) and the release factor assumptions from the applicants (with minor adjustments for correction), the total releases to the environment are calculated as 5.17 tonnes HBCDD, of which 3.2 tonnes are to be released, delayed by decades, from demolition and disposal. The total release equates to a release factor of 0.016%. This release factor would also apply to greater or lower use tonnages*."[77]

Breaking down this number by facility would provide citizens precise information of how much they, and their surrounding environment, are exposed to a specific substance of concern. This allows for public scrutiny, and pressure on enforcement. It would also empower investors to make informed choices on their investments away from SVHC-businesses.

ECHA has just built a new platform for downstream users to notify of the use of SVHCs, with a built in capability to request confidentiality for the information submitted. ECHA considers the only compulsory information the companies have to provide to be the name and location of the companies, the authorisation number and any data required by the authorisation itself. Other information, such as the volume used, the number of staff using the substance, the description of the use and the involvement in substitution activities are seen as voluntary. This platform should be used by ECHA as an opportunity to disclose directly the information notified by the downstream users, as well as, when a confidentiality claim has been made, the interest

[77] Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Opinion on an Application for Authorisation for Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane, Use: Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications (ECHA/RAC/SEAC:AFA-O-000004949-56-12/D) https://echa.europa.eu/documents/10162/0144eda8-0377-4cc6-aa94-c0de9a5a9456, page 13.

invoked by the downstream users, the justification given and ECHA's decision on the validity of the claim.

The extent to which ECHA will disseminate this information, and the way in which it will do it, remain unclear.

Improvement needed

ECHA should use the opportunity of having a new platform for downstream users' notifications to be more proactive in publishing information provided by downstream users, and consider the aim of REACH and of the authorisation process.

Where disseminating this information may lead to quicker substitution and more accountability for the companies concerned, it should consider the public interest in disclosure as overriding the commercial interest of the companies and disclose this information.

In any case, ECHA should review its interpretation of Article 118 and always disclose the tonnage of use in the context of the authorisation process.

4 Restrictions

The Restriction process under REACH aims at addressing unacceptable risks to human health and the environment deriving from the manufacturing, use or placing on the market of chemicals. Through a restriction, following the opinions of ECHA committees, the Commission can impose conditions on the use of a substance or ban certain uses of it. The Restriction process already existed before REACH came into force and was regulated by Directive 76/769/EEC.

Unfortunately, under REACH, as it was argued by a 2017 report by the EEB,[78] restrictions have become an extremely burdensome tool and are losing their potential to mitigate the negative effect that certain uses of hazardous chemicals can create. Since the REACH restriction process entered into force, the pace of restrictions has not significantly increased, while the scope of the final restrictions has narrowed.

While many aspects of the restriction process need to be improved, this report will focus on one practice that lacks transparency and can lead to an unjustified continuous presence of hazardous substances into the environment. This practice is the inclusion of unassessed derogations to restriction proposals by ECHA's SEAC.

Under REACH, restrictions are proposed by Member States or by ECHA, when requested by the Commission. Once a restriction is proposed, SEAC's role is to prepare a draft opinion on

[78] See, EEB, Restricted Success, EEB appraisal of Restriction under REACH, June 2017.

the suggested restrictions and on the expected socio-economic impacts, if any. A public consultation is also opened.

In the authorisation process, the public consultation is an opportunity for the Committees to receive new information on the existence and feasibility of alternatives. As mentioned earlier (3.1.2.), SEAC tends to disregard contributions from third parties giving information on existing alternatives, depriving the public consultation of any effect. In the restriction process, the public consultation attracts both the proponents and the opponents to the restriction and the latter can be very vocal. ECHA's scientific committees have been prone to take at face value many unsupported requests for longer transitional periods and derogations from the scope of restrictions. The EEB report demonstrates that ECHA's Committees frequently narrow the scope of the restrictions initiated by Member States or by the Commission. [79]

The resulting situation is that information received during the public consultation tends to be given more weight when it supports the least ambitious control of chemical risks. For example, for the restriction on 'PFOAs', SEAC included, at a late stage of the opinion development process, derogations for spare parts, latex printing inks, textiles treated for worker protection, filtration systems, non-implantable medical devices, nano-coated materials, and firefighting foams. These derogations will allow several tonnes of 'PFOAs' and 'DecaBDE', both extremely dangerous substances and extremely persistent in the environment, to be emitted without proper justification.

Similarly to the public consultation in the context of Authorisation, there is a lack of transparency on the criteria ECHA uses when deciding whether or not to take into account information submitted in the public consultation.

Improvement needed

ECHA should review the way in which it assesses information submitted in public consultations in the context of restrictions. It must disclose the criteria that the information needs to fulfil in order to be taken into account.

ECHA should ensure that the burden of proof is equivalent whether the consultation contributors argue for a broader or a narrower scope of the restriction.

5 Other issues

This section covers two ways in which the implementation of REACH could be made more transparent. First, by improving transparency of the Classification and Labelling Inventory, which is deeply connected to REACH. Second, by improving the organising of the relevant information through the creation of a register, needed more than ever now that many decisions, guidance, opinions, etc. have been adopted in the implementation of REACH.

[79] Ibid, page 10-12.

5.1 Classification and Labelling (C&L) Inventory

REACH introduced a Classification and Labelling (C&L) Inventory to ensure that classifications (and consequent labelling) of all hazardous substances manufactured in or imported into the EU are available to all and ensure the smooth running of the REACH system.[80] The provisions were later moved from REACH to the CLP Regulation.[81] The inventory allows citizens to know the potential risks of substances that do not have a harmonised classification and implements a consistent approach on the communication of their hazards and risks.

Under the CLP Regulation, substances and mixtures placed on the market must be classified according to their physical, health and environmental hazards[82] and notified to ECHA.[83] This information must be included in the C&L Inventory.[84] The Inventory is publicly available over the Internet and free of charge.[85]

According to CLP Art. 16(1) '[m]anufacturers and importers may classify a substance differently from the classification already included in the [C&L Inventory], provided they submit the reasons for the classification to the Agency'. If differing entries are substantiated (e.g. due to varying impurities), they are necessary and thus justified. In order to avoid different entries in the inventory for the same substance,'the notifiers and registrants shall make every effort to come to an agreed entry'.[86]

In its 2016 report ECHA notes a 'considerable divergence in the self-classifications for many substances'.[87] This phenomenon became not least visible with the introduction of 'brief profiles' for certain registered substances that also depict a breakdown of all substance specific C&L notifications.[88] ECHA identified 'difficulties in identifying and contacting each other' as one central constraint impeding notifiers and registrants from finding agreed entries.[89] In 2013, the agency therefore launched and, together with industry associations, promoted a platform to encourage these actors to contact each other and to proactively enhance the quality of C&L information. However, due to the lack of use of the platform, it has been discontinued.[90]

The C&L Inventory objectives to ensure harmonised protection and reliable C&L information are thus currently being put at risk.

In order to support industry in reaching agreements on self-classifications, ECHA recommends the 'Commission should consider changing the CLP Regulation to allow the sharing of contact

[80] Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} {SEC(2003 1171}, COM/2003/0644 final, paragraph 1.10.
[81] REACH Title XI (repealed) and CLP Articles 39-42.
[82] CLP Art. 1(b)(ii) and 3.
[83] CLP Art. 40; unless ECHA has already retrieved classification information from a registration dossier for the respective substances as such or in a mixture, cf. the information requirements in REACH Art. 10(a)(iv).
[84] CLP Art. 42.
[85] REACH Art. 77(2)(e).
[86] CLP Art. 41.
[87] ECHA (2016), Report on the Operation of REACH and CLP 2016, doi: 10.2823/760148, https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf, p. 118.
[88] See e.g. the brief profile for silicon dioxide at https://echa.europa.eu/de/brief-profile/-/briefprofile/100.028.678 (both 3.5.2017).
[89] ECHA (2016), Report on the Operation of REACH and CLP 2016, doi: 10.2823/760148, https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf (3.5.2017), p. 118.
[90] See https://echa.europa.eu/de/regulations/clp/cl-inventory/cl-platform; cf. https://chemicalwatch.com/47664 (both 3.5.2017).

details of notifiers'.[91] Making 'notifier details publicly available' would also be welcome by certain downstream user organisations.[92]

We agree that publication of notifier details, including names, would contribute to fulfilling the objectives of REACH, and of the C&L Inventory in particular. Such transparency would provide the basis for economic actors to get in contact with each other and ensure their compliance. In addition, related public pressure would increase incentives for these actors to ensure quality of their C&L submissions; pressure that ECHA and national enforcement authorities cannot create due to the sheer volume of information in the database.[93]

Although the CLP does not specifically require ECHA to publish the names of notifiers of C&L, no legal obstacle exists to such publication. EU law already provides that all information can be made public and provides for an obligation for public institutions to disseminate environmental information.[94] ECHA should create a system whereby companies are at least given the option to make their name public. As – since late 2012[95] – names of REACH registrants are generally publicly accessible, the same rationale could apply to CLP.

Improvement needed

Harmonisation of the classification of hazardous chemicals contributes to improving citizens' access to information on chemicals to which they may be exposed, as contradictory classifications are not easy to understand.

ECHA should take the initiative to put in place steps that effectively allow the CLP inventory to achieve its harmonisation goals. As for REACH, ECHA can provide notifiers with the option to claim that their name remains confidential if a justification exists.

5.2 The 'register of documents'

Since its creation ECHA has issued several thousands of decisions while implementing REACH: it granted over 60,000 registration numbers; granted or rejected about 2,300 confidentiality claims; adopted over 1,000 dossier evaluation decisions, and almost 1,000 testing proposals decisions; and made 174 decisions on including substances of very high concern in the candidate list. ECHA also generates thousands of other documents, scientific and regulatory. Only a fraction of this information is made available to the public. In some cases, even though it is made available, it is not easy to find.

To make the right of access to information effective, the EU Regulation on Access to Documents[96] provides for the obligation for all EU institutions to have a register of documents to which access may be given in electronic form (Article 11). The Regulation provides that for each document the register shall contain a reference number, the subject matter and/or a short

[91] ECHA (2016), Report on the Operation of REACH and CLP 2016, doi: 10.2823/760148, https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf (3.5.2017), p. 118.
[92] See the example of the International Molybdenum Association at https://chemicalwatch.com/50858 (3.5.2017).
[93] By 2 December 2016 the C&L Inventory contained 124.590 entries, see https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database (3.5.2017).
[94] Regulation 1367/2006, Article 4.
[95] See https://newsletter.echa.europa.eu/de/home/-/newsletter/entry/1_13_registrant_names (3.5.2017).
[96] 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, (
OJ L 145, 31.5.2001, p. 43–48)

description of the content of the document and the date on which it was received or drawn up and recorded in the register. The information included in the register should not disclose any information that may be protected as confidential for commercial or other reasons. This commitment is reiterated with specific regard to environmental information in Articles 5(2) and (3) of the Aarhus Convention, and Article 4(1) of the Aarhus Regulation, which states that, "*Community institutions and bodies shall organise the environmental information which is relevant to their functions and which is held by them, with a view to its active and systematic dissemination to the public by means of computer telecommunication and/or electronic technology in accordance with Articles 11(1) and (2), and 12 of Regulation (EC) No 1049/2001.*"

To our knowledge, ECHA does not have a register or an official journal as a one-stop-point to access and organise all the information it holds. ECHA is however considering the creation of a database for EU chemical regulation, following a request from the industry to create a 'substance regulation navigator'.[97] Such a tool would be a step in the right direction.

As an EU institution holding a large amount of environmental information, ECHA has the obligation to organise such information with a view to disseminating it, but also has to make the body of information that it holds and generates easily identifiable by interested parties. After all, as stated by the Aarhus Convention, public authorities hold environmental information **in the public interest**.[98]

Conclusion

Since its creation 10 years ago, ECHA has improved the dissemination of information it collects. However, its commitment to transparency falls short in many ways. It does not fulfil the minimum requirements set by REACH on information that must be made available by default (exposure scenarios, existence of a Chemical Safety Assessment, individual tonnage bands), and it disregards the obligations set in the Aarhus Regulation and in the Regulation on Access to Documents.

In addition, it fails to use transparency as a tool to empower third parties – civil society, citizens, consumers, investors or alternative providers - to contribute to the implementation of REACH. ECHA does not have unlimited capacities and overly depends on information provided by industry. This should spur ECHA to proactively disclose information so that third parties can scrutinise the information provided by companies, meaningfully contribute to the decision making process and ultimately make informed choices pushing companies to substitute hazardous chemicals with safer alternative technologies.

[97] See Clelia Oziel, 'Echa defers decision on EU legislation 'finder' to next year', Chemical Watch 8.11.2017. See also the update of the ECHA Transparency Approach adopted at the 45th Meeting of the Management Board 30-31 March 2017
[98] Aarhus Convention, Recital 17.

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