ClientEarth

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Demand #2 for REACH reform

No data, no market: from slogan to reality

The "no data, no market" principle of REACH 1 promised to lift the veil hiding the reality of the chemical universe in the EU by requiring companies to develop and provide information on the properties of their chemicals as well as their use. And if REACH 1 had set up the conditions to make it a reality, then the market actors would get the information they need and the EU institutions and States, also equipped with better understanding, would expend far fewer resources figuring out what and how to regulate.

This unfortunately failed to happen as the information requirements did not cover all substances, were too vague for public authorities and consumers to get meaningful information on use and were insufficient to ensure information flow in the supply chain.

Therefore, REACH 2 must create the conditions for "no data, no market" to become a reality, by strengthening and broadening the registration obligations, creating new obligations for downstream users to send information on use when a regulatory process is launched and improving access to information for all market actors.

Why is it needed?

Uncover hazardous chemicals and their use patterns

The REACH obligations on the registration and notification of substances were supposed to lift the veil hiding chemicals in our everyday lives. However, the vast majority of the ~100,000 monomer substances on the EU market are not submitted to registration and therefore fly below the radar.[1] There is still an extensive lack of knowledge on which substances are hazardous, because information requirements targeting, for example, endocrine disruptive chemicals (EDCs) or polymers, are entirely missing or linked

[1] EEA 2020, SOER chapter 10, Chemical pollution.

with unfit regulatory triggers (tonnage). Of the ~26,000 substances that have been registered, maybe 500 are truly studied, tracked and understood.[2]

As acknowledged by the REACH reform impact assessment submitted to the Regulatory Scrutiny Board, the registration dossiers are lacking meaningful data on chemical uses.[3] Requirements in the legal text on central use information are missing, such as technical functions, product types, process categories and specific tonnages. Much of the data provided by registrants is likely outdated, with only 10% of registrations updated each year.[4] Information on alternatives for substances of very high concern (SVHCs) is usually missing.[5] These shortcomings in data availability deeply undermine public authorities' capacity to make appropriate risk management decisions about the most hazardous substances.

Considerably ease the work of decision makers

Under the current regime, when enacting a restriction based on Art. 68, 69-73, authorities have to establish unacceptable risk. They describe this task as "*highly complex and time consuming*",[6] which is due in big part to the data gaps listed above. As noted by the submitted Impact Assessment, between January 2011 and March 2022, only 28 restrictions were enacted - an average of 2.5 per year compared to the 11 yearly restrictions expected when REACH was adopted.[7] Only six countries regularly launched restrictions, producing nearly 90% of these dossiers.[8] When it comes to the fast-track restriction of Art. 68(2), the way the Commission implemented it for articles turned out to depend on heavy data inputs.[9] Finally, in the REACH authorisation process, the overreliance on the applicants' data blinded RAC and SEAC to the best practices on the market.[10]

Support transparency on chemicals for users and society

Companies producing mixtures or articles need to know the hazardous chemicals present in the raw materials they buy, so they can ensure the safety and sustainability of their own products and provide information to interested consumers and investors. REACH 1 created mechanisms to ensure information flow to customers and consumers, as well as access to information for the general public – but they have not been sufficient.

For customers, Art. 31 requires suppliers of hazardous substances and mixtures to provide a Safety Data Sheet (SDS) with information on the concerned substance(s) and safe use. Enforcement agencies however experience a "*persistent problem of deficiencies in quality of the SDSs*".[11] In addition, there is no harmonised format for electronic SDSs, which unnecessarily complicates data handling for customers. According to Art. 33(1) suppliers of products ('articles') have to actively inform their customers about SVHCs present in articles, but in practice duty holders appear unaware of this obligation or simply

[2] EEA 2019, SOER chapter 10, Chemical pollution.
[3] Impact Assessment submitted to the Regulatory Scrutiny Board (2023), 9. See also ECHA's 2021 report on the Operation of REACH and CLP, pp. 66 et seq.
[4] ECHA 2021, report on the Operation of REACH and CLP, p. 41.
[5] ECHA 2021, report on the Operation of REACH and CLP, p. 8.
[6] Annex to the Impact Assessment submitted to the Regulatory Scrutiny Board 2023, p. 478.
[7] Ibid, p. 474.
[8] ECHA's 2021, report on the Operation of REACH and CLP, p. 57.
[9] See the approach concerning "Use of article 68(2) for CMRs in articles" presented to CARACAL in 2014.
[10] SWD(2018) 58, PART 5/7, p. 110; see also our 2021 analysis Socio-economic assessment and REACH authorisation (clientearth.org) .
[11] ECHA 2019, FORUM Report on Improvement of Quality of SDS, p. 7.

disregard it.[12] Downstream actors hence are lacking data on the most harmful chemicals in their products. Downstream actors such as H&M group are calling on the Commission to enhance transparency[13] and would like to see full traceability about chemical use in production supply chains.[14]

For consumers, Art. 33(2) aimed to empower them to request information on SVHCs in products from the suppliers. However, this ambitious "right to know" has in practice degenerated into a "right to ask" since product suppliers are not capable, aware or sometimes not willing to sufficiently respond.[15]

For investors and civil society, Art. 119 grants electronic public access to information on registered substance properties and exposure, as well as their manufacturers and importers. ECHA, as the manager of dissemination, however withholds data that is crucial to guide investments and public opinion, such as the tonnage-band per registrant, names of the companies behind Only Representatives[16] and names of companies non-compliant with their registration obligations.

What should it look like?

Strengthen and broaden information requirements at the registration stage

Hazards

In the architecture of REACH, the information submitted by the industry under the registration regime should lay the foundations for any risk management concerning industrial chemicals in the EU. However, as also raised by the Chemical Strategy for Sustainability, the current information requirements fail to acknowledge crucial hazard classes, polymers and combination effects of chemicals and leave loopholes for low-volume substances. We request fulfilment of the following commitments made by the European Commission:[17]

- *Endocrine disruptive chemicals (EDCs)*: The Chemicals Strategy for Sustainability promises to "*ensure that sufficient and appropriate information is made available to authorities to allow the identification of endocrine disruptors by reviewing and strengthening the information requirements across legislation*".[18] Full identification of all EDCs is crucial to allow for appropriate risk management, which entails strict obligations concerning new tests when data is missing.
- *Neurotoxicity and immunotoxicity*: The Commission has to deliver on its commitment to "*enable an effective identification of substances with critical hazard properties, including effects on the nervous and the immune systems*".[19]

[12] SWD(2020) 247, p. 34; cf. ECHA 2021, report on the Operation of REACH and CLP, p. 25.
[13] See the open letter of 7 major players and ChemSec of April 2022.
[14] See the "Theory of Change" for a non-toxic circular economy report from a workshop hosted in May 2022 by the LIFE AskREACH project.
[15] See for example this brief assessment by the LIFE AskREACH project, having monitored the communication between 80,000 consumers using the App Scan4Chem and 7,000 companies.
[16] Mandatory to submit as per Commission Regulation (EU) 2022/477, OJ L 98, 25.3.2022, p. 38–53.
[17] See for detailed assessments the report Waiting for REACH prepared by EEB and CHEM Trust (March 2023).
[18] COM(2020) 667, p. 11.
[19] COM(2020) 667, p. 20.

- *Low tonnage substances*: REACH 2 needs to expand the information requirements for substances manufactured or imported at 1-10 tons to allow for the full identification of hazardous properties, i.e. not only carcinogenicity, [20] but also repeated dose toxicity, other long-term toxicological and ecotoxicological endpoints, persistence and bioaccumulation potential, as well as properties affecting the endocrine, nervous and immune systems. Besides, supply chain actors must be obliged to perform a chemical safety assessment.
- *Polymers:* Following the Commission's commitment, [21] REACH 2 must introduce a new legal regime which ensures: a) oversight of polymers placed on the EU market and proper assessment of their hazards and risks by industry, b) that risk management measures are implemented by the industry and c) that authorities are equipped with strong (perhaps expanded) mandates for regulatory risk control.
- *Combination effects:* REACH 2 must introduce mixture assessment factor(s) for the chemical safety assessment of substances to "*ensure that risks from simultaneous exposure to multiple chemicals are effectively and systematically taken into account*". [22]

Use

The REACH registration aims to gain oversight of chemicals' uses along their life cycle, by obliging supply chain actors to generate the information needed to avoid and mitigate risks, and thereby creating a knowledge base for authorities to target specific chemicals and uses proven to require regulatory control. To that end, REACH provides a framework for chemical companies and their customers to communicate and interact, in order to generate accurate data on uses and their risk. These obligations (Art. 7(4), Art. 10(a)(iii), 14(4), 37(4) etc.), however, rely on unfit generic legal concepts such as "use" and "brief description of use", which are far too vague to ensure companies are providing the information necessary to understand all relevant patterns of use. There is thus a need for new registration provisions tailored to deliver the necessary clarity on function, scale of use and regulatory needs. This will require, among other things, that companies define categories more specifically [23] for example, by differentiation of sector, technical function, article, product, mixture and process categories.

The new registration regime under REACH2 should require the following:

- Information requirements regarding the identity of companies and parent companies (including companies behind Only Representatives).
- Strengthened obligation of downstream users to communicate with upstream operators (Art. 37).
- Information requirements on more specific use categories, completed by guidance and pre-filled fields in IUCLID [24]:
    - Sector(s), with differentiation according to market structures of downstream use sectors;
    - Function(s) of substances in products and preparations;
    - Product category(s), with sub-category(s) by application;

[20] COM(2020) 667, p. 20.
[21] COM(2020) 667, p. 20.
[22] COM(2020) 667, p. 12.
[23] As recommended in Advancing REACH - REACH and substitution (umweltbundesamt.de).
[24] International Uniform ChemicaL Information Database.

  - Process category(s), with sub-category(s) by application;
  - Article category(s);
  - Intended transformation (if any).
- Information on production, import and export volumes:
  - Tonnage per registrant and tonnage for intermediate use;
  - Total volume per use, including product categories and total intermediate use (confidential upon request).
- Obligation to include information relevant for exposure required under other EU laws (for example on Occupational Health and Safety, Water Framework Directive, Industrial Emissions Directive).
- In the context of the Chemical Safety Report (CSR), obligation to do an exposure assessment per similar, precise use.

To prevent companies from "over-listing" uses, thereby unnecessarily binding public resource, appropriate mechanisms such as an additional information requirement introducing a mandatory exposure assessment per use would be required. Besides, considering the current high level of non-compliance, new incentives to comply will be needed (see brief on our Demand #5 on Sanctions).

As these new provisions alone cannot fully overcome the lack of incentives in the REACH registration for customers to report upstream their specific use patterns, we propose new information requirements for downstream users regarding their chemical uses linked to some of the most hazardous substances (see below).

Updates

Implementing Regulation 2020/1435 clarifies when companies have to update their registrations in case "relevant new information" becomes available. Additional triggers are needed to motivate registrants to reflect on and update their data.[25] We propose:

- an obligation to update and complete registration dossiers for substances placed on the Candidate List, or targeted by a new restriction initiative upon entry in the Registry of Intentions; and
- a general need to update at least every 2 years.

New obligations for downstream users to provide information on use at regulation stage

Having a good understanding of all current uses of chemicals, including essential uses, is a prerequisite for adequate regulatory risk management. Under REACH 1, relevant information, however, is not readily available when authorities launch regulatory processes, as it is provided too late by the industry and lacks proper systemisation and rigour. The new registration obligations proposed (see above) alone cannot plug all existing loopholes, as not all substances are registered and the information on use can be limited for

[25] ECHA 2021, report on the Operation of REACH and CLP, 67 recommends "for hazardous substances requiring exposure assessment, regular updates of the annual tonnages and information on use volumes".

upstream actors. In order to fill the current data gaps, a new mechanism is needed to ensure the notification of key information from downstream users to public authorities very early in the regulatory process, backed up with strong incentives for completeness and accuracy.

Scope

The new obligation would apply to all substances from the Candidate List[26] or that are subject to a new entry on the Registry of Intention for restrictions.

Notification

Downstream users (Art. 3(13)) and suppliers of an article (Art. 3(33)), should be obliged to report to the Agency for any use of any substance:

- sector(s), with differentiation according to market structures of downstream use sectors,
- function(s) of substances in products and preparations,
- product category(s), with sub-category(s) by application,
- process category(s), with sub-category(s) by application
- article category(s),
- intended transformation (if any),
- information on production, import and export volumes: total volume per use, including product categories and total intermediate use (confidential upon request),
- specific information on technical function, substitution plans including efforts done and planned, and potential alternatives,
- specific information on risk management measures in place and,
- information relevant for exposure required under other EU laws (for example on Occupational Health and Safety, Water Framework Directive, Industrial Emissions Directive).

Strong incentives for compliance

We propose that companies in breach of the new obligations are excluded from the right to apply for authorisation and cannot benefit from derogations under the reformed authorisation and restriction schemes (see briefs on our Demand #3).

New powers for ECHA and Member States to fill data gaps

Dependence on what data companies (want to) submit to fulfil their obligations is a structural weakness of any information collection scheme. Shortcomings in data provision – if it comes too late or is incomplete - slows down effective risk management, placing a burden on human health and the environment. Moreover,

[26] Also suggested by Advancing REACH: Interplay of the REACH Processes (umweltbundesamt.de), p. 34. Similarly, the Impact Assessment submitted to the Regulatory Scrutiny Board looks into ”Option #7: Companies would be obliged to provide information on uses, tonnage per use and exposure upon inclusion in the candidate list.”, p. 25.

scientific progress may trigger new data needs of authorities implementing their risk management mandate that are going beyond existing information requirements.

Duty to respond to information requests

We propose to create a new duty for any actor in the supply chain of a substance, mixture or article containing a substance, as well as their competitors and association of actors to respond to requests from ECHA and competent authorities.[27] Those requests are not limited in scope, and can address, for example properties, use, function, exposure, potential alternatives.

Market analysis

REACH 2 should strengthen the role of ECHA to process and systematise submitted use information to prepare regulatory measures. To break the dependency on industry data and fill data gaps ECHA should be allowed to commission a market analysis (by a consultant, funded by fees on SVHC use, see our Demand #3 on Authorisation) to identify best practices and support authorities' assessment of uses, exposure and alternatives.

Strengthened access to information for investors and society at large

According to Recital 117 of REACH "*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*." Art. 119 defines data items from registration dossiers to be published by ECHA, Art. 118 includes the conditions to access even more information. While all this technical information might not be useful for consumers, it can provide a rich source for investors and civil society representing consumer interests. These actors can use chemical data to create market signals and substitution pressure, thereby also enhancing competitiveness and innovation of the EU chemicals sector.

But, today, regarding chemical producers, investors and civil society only have limited information to inform their decisions. The reform of Art. 118 and 119 should refine and expand ECHA's mandate to grant access to the following items:

- Tonnage per registrant, or more flexible tonnage band per registrant;
- Tonnage for intermediate use.

Today there is only access to aggregated tonnage bands per substances but no access to (rough) quantities of the chemicals each company produces and what their regulatory obligations and risks are as a result. This is because ECHA, which holds a lot of this data, has been reluctant to make it public and has for years interpreted the REACH Regulation in a way that restricts transparency unduly.

- Name of companies and their parent companies;
- Name of companies (and their parent companies) behind Only Representatives.

[27] See also Art. 36 with a similar yet insufficient scope. See also ECHA 2021, report on the Operation of REACH and CLP, 66 (emphasis added) recommending that it would be "efficient for authorities to have information on use and volume per use available at an earlier time, or to have the possibility to request it, to avoid timing and efficiency issues in the risk management processes".

Following a General Court[28] judgement ECHA needs to proactively disseminate the names of registrants. To enhance legal clarity, this practice should be formalized as a legal obligation and consequently publishing names of parent companies[29] behind registrants and Only Representatives should become mandatory as well.

- Information on use in the registration dossiers;
- Information on use from the downstream user notifications.

Use data subject to the proposed new obligations for registrants and downstream users (see above) should by default be disseminated with only a limited scope to claim confidentiality.

- All information submitted for authorisation (with strict exceptions for commercial secrets).

This would help third parties, and in particular alternative providers, to contribute meaningfully to the objective of the authorisation process – to promote the replacement of SVHCs with safer alternative substances or technologies.[30]

Meaningful communication on chemicals, and traceability

Digitalisation of the Safety Data Sheet (SDS)

The SDS should support communication about hazards and safe conditions of use from actors further up in the supply chain to their customers. It was used already before REACH, but non-compliance is nevertheless still very high[31] while its usefulness for the downstream users is low (due to varying quality, scattered formats etc.). One way to ease this is introducing a harmonised electronic format for the preparation and exchange of a digital SDS that contains machine-readable information.[32] Such a format would improve usability of the SDS by making the information it carries available for all sorts of evaluations facilitated by IT tools. Providing such a clear legal framework would additionally reduce complexities for suppliers, their customers as well as for authorities keen on improving compliance rates. Harmonising digital communication does however not preclude the parallel existence of a physical SDS. The new framework should oblige the supplier to provide a paper version if requested by customer.

Substances in articles

Supply chains

Art. 33(1) requires the supplier to inform its customers about any SVHCs present in articles above 0.1% by weight. The provision aims to kick-start an information flow down the supply chain that should trigger the purchase of safer articles and materials and inform risk management with relevant “safe use information”. This data flow simultaneously creates the basis to answer consumer right to know requests (see below). In practice, companies have largely ignored their obligations. The Commission in its 2020

[28] T-245/11, ClientEarth, ChemSec v. ECHA, ECLI:EU:T:2015:675.
[29] A new information requirement needs to be created.
[30] See our report 10 years in: time for ECHA to disseminate strategic information to empower third parties | ClientEarth
[31] ECHA 2019, FORUM Report on Improvement of Quality of SDS,
[32] All stakeholders in the public consultation supporting the impact assessment welcomed this regulatory option, Annex to the Impact Assessment submitted to the Regulatory Scrutiny Board 2023, p. 16.

review of the provision observed few improvements in the implementation,[33] lack of clarity on the legal obligations being a major reason.[34] Attempting to improve availability of SVHC information, the legislators created an obligation under the Waste Framework Directive to notify to ECHA articles that contain SVHCs. Companies have to upload the information required by Art. 33(1) REACH to the SCIP database. However, this notification scheme obviously cannot work in the absence of the SVHC data flow in the supply chains. We therefore propose to clarify and expand the obligations of Art. 33(1):

- Add minimum requirements on relevant safe use instructions;
- Clarify that companies must use a structured management approach to Art. 33(1) implementation, which includes proactive requests by the customers when suppliers do not provide (plausible) SVHC information (main elements of the approach could be outlined in an Annex);
- Clarify that the relevant SVHC information must be available upfront before purchasing (for example in a catalogue) so that customers can actually avoid SVHCs in their products;
- Clarify that after a Candidate List update the article supplier updates its SVHC report to the customers;
- Make the information subject to the SCIP notification mandatory in the context of REACH and develop guidance to standardise reported data to maximise its usefulness:
    - name of the article and other names(s)
    - primary article identifier and other identifier(s)
    - article category (with sub-category)
    - production in EU
    - complex object component(s)
    - concentration ranges for the SVHCs
    - mixture or material categories
    - update when SVHC present in an article has been substituted by a safer alternative.

In a broader perspective, Art. 33 and the associated SCIP notification are the centrepieces of the current regulatory strategy to improve transparency of substances in articles. Though the focus here is only on SVHCs. As of March 2023, this list contains 233 entries for (groups of) substances. Several wide-ranging restrictions are currently being prepared (e.g., PFAS, bisphenols), and given the promise of the Chemicals Strategy to phase out the most hazardous substances in consumer products, a number of other restrictions will follow.[35] These restrictions will address substances having a harmonised classification and additional substances not (yet) placed on the Candidate List. The current legal framework fails in creating traceability of these substances in articles: downstream users do not know which chemicals are present in the articles they buy and transform into consumer products. Consequently, they have very limited capacities to actively substitute these substances – for example, in the face of a looming restriction. This lack of traceability - the ability to determine which substances are in mixtures and products - is also an obstacle to the risk management of polymers and the calculation of the environmental footprint of chemicals, i.e. two elements

[33] SWD(2020) 247 final.
[34] See Advancing REACH: Substances in Articles (umweltbundesamt.de).
[35] SWD(2022) 128.

of the REACH reform to which the Commission has committed.[36] Not least this lack of traceability impedes Sustainable Product Policies that aim to enhance circularity of product and material flows while avoiding toxic-cycles.[37] Taking into account the enabling function of chemicals traceability in the context of REACH and beyond, we propose:

- Introduce a task for the Commission to assess regulatory options on how to enhance traceability of substances in articles,[38] based on an approach for the identification of products and articles that is coherent with REACH Art. 33, SCIP and any new instrument developed under the Sustainable Product Policies (for example the Digital Product Passport).

Consumers

Art. 33(2) was intended the central mechanism in REACH to give consumers transparency on the most hazardous chemicals in products to allow for informed consumption decisions. The design of this "right to know" on SVHCs in articles is however flawed: upon request by the consumer, article suppliers are obliged to name any SVHCs present above 0.1% as well as relevant safe use information. If SVHCs are not present, no duty to reply exists, leaving consumers in the lurch. The changes needed to turn this mere right to ask into a strong right to know are:

- Insert obligation to answer a request in any case;
- Reduce the 45 day period for companies to reply - towards the immediate automated provision of the SVHC article information;
- Enhance direct access for consumers by linking SCIP with the article database and smartphone app developed by the EU LIFE AskREACH project.

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[36] COM(2020) 667, p. 20.
[37] COM(2020) 98, p. 13.
[38] See for example the options discussed in the AskREACH workshop report (2023).