

European chemicals regulation needs more transparency

To meet the challenges of chemical risks in everyday life, risk assessments under the REACH registration process must be improved. One key element in that transformation is to introduce more transparency.

We use in our daily lives a wide range of chemical-intensive products such as construction materials, textiles, cars, electronics and toys – and the use of chemicals in society is increasing every year. This requires an improved ability to understand, identify and manage potential chemical risks to human health and the environment.

In 2007, the European chemicals legislation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) was adopted to ensure that risks with chemicals are adequately controlled. However, the processes for identifying and taking appropriate regulatory measures against potentially harmful chemicals are still slow in relation to the current production rate of chemicals put on the European market.

To meet the challenges of our time regarding chemicals in everyday life, the structures for control and gathering of chemical information under the legislation must be improved. One action that could increase the precondition for using REACH to identify chemicals of concern for human health and the environment is to introduce significantly more transparency in the registration process.



Photo: André Maslennikov/Azote

There is need for more transparency in the chemicals regulation.

RECOMMENDATIONS

To the European Commission:

- Investigate and suggest changes in the REACH legislation that further increase the transparency.
- Investigate the possible negative consequences of conflicts of interest in the REACH registration process, and consider the option of having an independent third party performing chemical risk assessments.
- Increase the number of dossiers that ECHA has to review, to allow for an increased quality in the control of the chemical risk assessments.

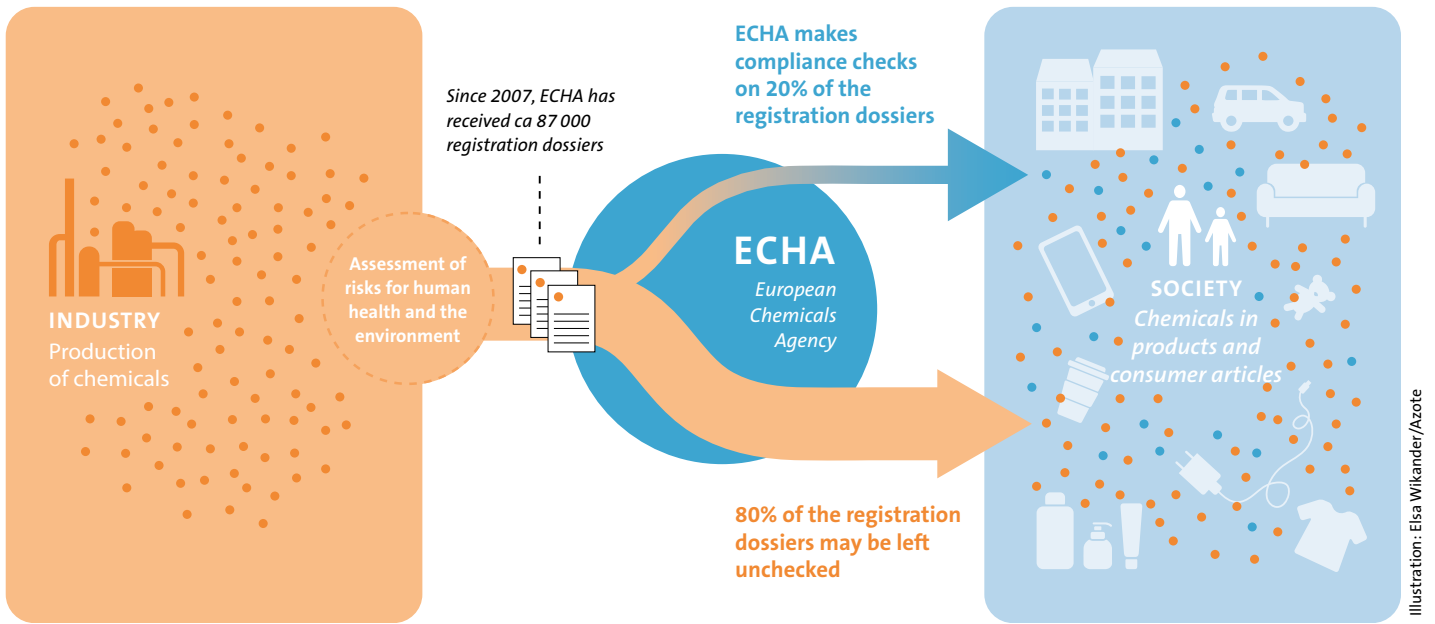
To the European Chemicals Agency:

- Further explore how dissemination of risk assessments and toxicity studies can be enhanced within the current REACH legislation.
- Implement and enforce a common method with clear criteria and guidance for evaluating toxicity studies, as well as a template for transparent reporting of assessments.

To the chemical industry:

- Support transparency initiatives and make the toxicity studies used for concluding on chemical risks fully available for independent scrutiny.

Regulation of chemicals under REACH



In the REACH legislation, the chemical industry is responsible for assessing risks for human health and the environment for chemicals registered on the European market. The registration dossiers are sent to the European Chemicals Agency (ECHA) where only a small percentage per tonnage band are to be checked for compliance with the REACH legislation. Recently ECHA announced an increase from 5% to 20%. Consequently, the majority of the registration dossiers will not be checked. According to the European Commission's own investigations, more than half of the dossiers that were checked turned out to be in-compliant.



Identifying and managing chemicals of concern is a cornerstone of the REACH legislation. But there is a lack of compliance from the chemicals industry, and the information provided is often not sufficient for authorities to identify and prioritise the need for action.



The registration process has an inherent conflict of interest. The responsibility for generating and evaluating (eco)toxicity data and performing the risk assessment lies with the producer or importer of the chemical, i.e. an actor that has a clear economic interest in the outcome of that process.

Why is transparency needed?

Identifying and managing chemicals of concern is a cornerstone of the REACH legislation. How well this is done depends heavily on the quality of the risk assessments provided by the chemical industry to the European Chemicals Agency (ECHA).

These assessments rely on information about the chemicals' toxicity, uses, foreseen exposures and risks, as well as instructions for safe handling. The current distribution of responsibilities and the characteristics of the REACH legislation has challenges of direct relevance for transparency:

- Firstly, the registration process has an inherent conflict of interest. The responsibility for generating and evaluating (eco) toxicity data and performing the risk assessment lies with the producer or importer of the chemical, i.e. an actor that has a clear economic interest in the outcome of that process.
- Secondly, it is unclear if the REACH legislation can deliver comprehensive and correct assessments suitable for decision support. Both the German Federal Institute for Risk Assessment (BfR) and the European Commission have performed evaluations of REACH registrations – and they both conclude that there is a remarkable lack of compliance from the chemicals industry, and that the information provided is often not sufficient for authorities to identify and prioritise the need for action.
- Thirdly, ECHA performs compliance checks on a relatively small percentage of the registered risk assessments (20% per tonnage band). Consequently, 80% of the risk assessments provided by the industry may not be checked for legal compliance.

As of this year, ECHA increased the percentage of compliance checks from 5% to 20% per tonnage band. This is an improvement, but considering the high number of non-compliant dossiers this target has to increase further until compliance is significantly improved. Furthermore, the increased compliance check target

FIVE REASONS WHY REACH NEED MORE TRANSPARENCY

European chemical safety is built on a regulatory system that:

- apparently provides insufficient guidance to registrants on how to evaluate and summarize toxicity studies
- is susceptible to bias because it has an inherent conflict of interest relying on industry to show that the risks with their products are adequately controlled
- repeatedly has been shown to have a remarkably high level of non-compliance
- provides responsible agencies with limited resources to ensure compliance
- offers limited possibilities for third parties to scrutinize the risk assessments made by industry.

Source: Transparency within REACH? Regulatory risk assessment of industrial chemicals (Stockholm University, 2018)

should be combined with a demand for greater scope in each control since current compliance checks only address certain parts of the scrutinized dossiers.

To ensure protection of human health and the environment, there is an apparent need for an increased supervision and evaluation of the quality of the risk assessments performed under REACH. This calls for complete transparency, so that independent evaluation by third parties is made possible.

Poor reporting of environmental and health information

According to REACH, producers or importers of chemicals must report all available and relevant (eco)toxicological information in such detail needed to fully understand the reasoning and conclusion of their risk assessment. The information is collected in a dossier and provided to ECHA.

Unfortunately, the quality of these dossiers varies greatly. As a consequence, it is not always possible to understand and thereby assess how the producers or importers arrive at their conclusions on risk.

In a recent thesis from Stockholm University, *Transparency within REACH? Regulatory risk assessment of industrial chemicals* (2018), scientists examined 60 REACH registration dossiers, focusing on how scientific information was reported and used. The results show considerable variation in the quality of data evaluation and reporting. Among the observed discrepancies were omitted information on the design of toxicological studies, and incomplete reporting of toxicological effects. In addition, the amount of information registered varied greatly, from reporting comprehensive environmental and health information to merely providing a few summarizing sentences.

ECHA's current guidance on how to report scientific information for chemical assessments fails to guide the industry into delivering information suitable for decision-making.

Poor possibilities to scrutinize information

Confidential business information and intellectual property rights have strong protection in law. Consequently, toxicity studies commissioned by the chemical industry are not publicly available, and third parties, such as scientists and NGO's, have little or no possibility to use or scrutinize the information behind the risk assessments.

One way of increasing transparency is to make such confidential information public. This would require legislative changes or a different interpretation of the existing law on disclosure of information.

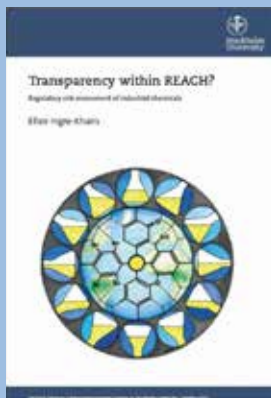
The movement towards increased transparency is already ongoing within the EU. In 2019, the European Parliament and the Council reached an agreement regarding the Commission's proposal to boost transparency in EU's General Food Law. The reform will require industry to make publicly available the complete toxicity studies used in risk assessments of chemicals that end up in our food, such as pesticides and food additives. It is equally important to make a similar reform also for the REACH legislation.

AUTHORS AND CONTACT

This policy brief is based on the thesis:

Transparency within REACH? Regulatory risk assessment of industrial chemicals

by Ellen Ingre-Khans at the Department of Environmental Science and Analytical Chemistry (ACES), Stockholm University.



Policy Brief authors:

Christina Rudén and Marlene Ågerstrand, Department of Environmental Science and Analytical Chemistry (ACES), Stockholm University.

For questions or more information, please contact the authors, christina.ruden@aces.su.se or marlene.agerstrand@aces.su.se.



Photo: Anette Rattfelt/Azote

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BALTIC EYE – BRIDGING THE GAP BETWEEN SCIENCE AND POLICY

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CONTACT

Marie Löf, Marine Ecotoxicologist
+46-8-16 38 55, marie.lof@su.se

Science and communication with focus on the sea

+46-8-16 37 18 | ostersjocentrum@su.se | su.se/ostersjocentrum

Baltic Sea Centre



Stockholm University