

## *EIPA Briefing 2021/1*

# **Enforcing EU chemicals policy: the multi-level pursuit of zero tolerance**

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In October 2020, the European Commission published a ‘Chemicals Strategy for Sustainability’. The Communication is subtitled ‘Towards a Toxic-Free Environment’, pointing to the vital importance of this sector in contributing to the goals of the Green Deal. Among the fifty or so measures listed was the proclamation of a ‘zero tolerance approach to non-compliance’. This is a response to long-lasting concerns over the low level of compliance by companies, as well as uneven enforcement by the EU Member States.

This Briefing discusses measures aimed at improving enforcement, and it draws attention to remaining challenges to ensure compliance with chemicals legislation.

## **Introduction**

The adoption of the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation in 2006 was considered a paradigm change in EU chemicals policy. REACH introduced new instruments for regulating chemical substances and created the European Chemicals Agency (ECHA). These instruments shifted the responsibilities of risk assessment and management to private actors, i.e., manufacturers, importers, producers and downstream users of chemical substances. To complement these self-regulatory instruments, REACH includes several provisions to strengthen enforcement.

In recent years, chemicals policy, including REACH and other legislation, has undergone extensive reviews. This briefing presents the most important problems of non-compliance that have been found in these reviews. It first gives an overview of the multi-level enforcement, which involves the agency, a network of national authorities and, most importantly for ensuring compliance, the enforcement authorities in the Member States. The briefing then presents the measures proposed in the Chemicals Strategy and discusses the continuing challenges of ensuring compliance.

## **Problems of multi-level enforcement**

European Chemicals Agency (ECHA)

The REACH regulation created ECHA and introduced the mandatory registration of all substances on the market. To this end, manufacturers and users of substances must submit to the agency a registration dossier providing information about risk assessment and management of the respective substance. Together with the Member States, ECHA conducts the compliance check of registration dossiers. Given the responsibilities of private actors for assessing and managing risk, effective enforcement is of utmost importance to ensure compliance with the ‘no data, no market’ principle of registration.

In the second REACH review in 2018, the Commission concluded that only one third of all registration dossiers are in full compliance with the respective information requirements. These requirements are often ambiguous, and the provisions in REACH do not provide for sufficient incentives for companies manufacturing or using substances to submit comprehensive and well-founded information. Although ECHA is entitled to check the compliance of dossiers, the agency is legally not required to check all dossiers, nor does it have the necessary resources to do so. The decision-making procedure of compliance check, involving the agency and Member States, is cumbersome and often time consuming. Most importantly, even if the check finds that the registration dossier is not in compliance, ECHA does not revoke the registration as it does not have the legal mandate to do so. The agency only revokes registrations in case of incomplete or outdated registrations.

### Forum

The provisions in the REACH regulation to strengthen enforcement are underpinned by the commitment to cooperation, coordination, and information exchange among the Member States, ECHA and the Commission. To substantiate this commitment, the regulation established the Forum for Exchange for Information on Enforcement (Forum). The Forum is composed of one representative per Member State with a role and experience in national enforcement. The tasks of the Forum are identifying and spreading enforcement strategies and good practice, coordinating enforcement projects and exchange of inspectors, developing working methods, and examining regulatory instruments under REACH with a view to enforcement.

To support these tasks, the Forum has developed a common enforcement strategy which guides enforcement activities by national authorities (latest version released in 2017). The strategy aims at a single, EU-wide enforcement strategy by detailing the priorities and strategies for national enforcement activities. The Forum conducts joint enforcement projects to harmonise enforcement in the Member States (the 10th enforcement project announced in March 2021). In addition, the Forum provides training and learning for inspectors, and supports the reporting of national enforcement activities.

Based on the evidence presented in the various reviews of REACH and other legislation, it is fair to assert that the Forum, within the limits of its legal remit, does contribute to the effectiveness of enforcement.

### Member States

The responsibility of Member States to enforce the requirements for private actors stemming from REACH and other legislation entails various enforcement activities such as guidance, inspections, fines, and legal action.

The second REACH review and the review of chemicals policy (other than REACH) in 2019 identified several challenges. In general, enforcement in the Member States is characterised by a high degree of diversity. There is significant variation in the institutional settings and national authorities' resources and capacities. Likewise, and despite the Forum's enforcement strategy, practices of enforcement vary in the Member States.

## The proposed measures to improve enforcement and continuing challenges

### Amendment of REACH

In the REACH review, the Commission concluded that the regulation was operating at satisfactory level and that no legal revision was needed. The reluctance of the Commission is partly explained by the fact that amending REACH is opening a 'can of worms'. Yet the Chemicals Strategy Action Plan includes several measures which require the amendment of the legal text.

The first is to extend the scope of compliance check to all registered substances. Given the magnitude of this task, however, the extension of compliance check is not merely a legal matter. It is primarily a financial challenge to provide ECHA with the necessary resources, and it is an administrative challenge to simplify decision-making on compliance checks.

The second is to introduce the possibility for ECHA to revoke registrations in case of non-compliance. However, given the political salience of this issue, it can be expected that revocations will only be a measure of last resort, whereas the agency will have to rely on other means, particularly coordination with industry and Member States to ensure compliance.

### Coordination, information exchange, and auditing

In the Chemicals Strategy, the Commission presents various measures that do not require the amendment of REACH. Due to the interaction of REACH and other legislation, coordination among national enforcement authorities is a prerequisite for effective enforcement. The 10th enforcement project by the Forum, for instance, will focus on integrated control of consumer products, thus inspecting requirements stemming from REACH as well as legislation on toys and electrical equipment. The Commission aims to increase the use of information technology to exchange information on chemicals legislation, and to focus on target areas of high risk of non-compliance such as online sales or imported products.

Moreover, the Commission proposes to reinforce EU capacities, notably the establishment of a European Audit Capacity to audit enforcement activities in the Member States. The scope of action of the European Anti-Fraud Office (OLAF) to address the problem of illicit chemicals shall also be extended.

The challenge here relates to the institutional and administrative features of national enforcement, as variance in terms of priorities and resources will remain. The Forum does not have the mandate to harmonise enforcement, and only supports and complements activities at national level. In most Member States, several authorities are responsible for enforcing different parts of REACH as well as other legislation and effective enforcement depends on domestic coordination. Institutional and administrative variance is exacerbated by different national interpretations of the legal provisions and varying priorities and strategies of national enforcement authorities.

## Conclusion

In March 2021, the Council adopted Conclusions endorsing the Chemicals Strategy, calling on the Commission, inter alia, to develop a roadmap for REACH amendment. In May 2021, the process of amending REACH has been initiated by the Commission with the publication of the inception impact assessment. The legislative proposal is planned for the end of 2022. Given the political salience of chemicals policy and the contested nature of the proposed measures, the policy making process will be characterized by controversy.

It can be expected that the Member States will not grant ECHA full autonomy in revoking registrations and there will be probably a strong role of Member States authorities in the respective decision-making procedures. In the Conclusions, the Council called on the Commission to provide further information on the potential European Audit Capacity, but the Member States will be reluctant to give the Commission great leeway to audit national enforcement activities. Although the Council encouraged the increase of enforcement capacities, it acknowledged at the same time, the leading role of the Member States as regards the cooperation of national authorities. Hence, multi-level enforcement is an enduring feature of chemicals policy irrespective of the prospect of amending REACH and, as the Council Conclusions demonstrate, national enforcement authorities will continue to play the leading role alongside the Commission and the agency.