

Stepping up enforcement of REACH: Cefic supports the revocation of registration numbers subject to a transparent legal process

Cefic supports the initiatives announced in the Chemicals Strategy for Sustainability to strengthen a zero-tolerance approach to non-compliance with the EU chemicals legislation. One of the initiatives proposed by the European Commission is to enhance the enforcement of the “no data, no market principle” by giving ECHA power to revoke REACH registration numbers of non-compliant dossiers.

Cefic believes that, with clear conditions and sound legal process in place, future action on revocation of registration numbers would ensure level playing field between EU and non-EU players and a higher degree of health and environmental safety.

The new system should include clear conditions and a sound legal process to ensure legal certainty for companies. It should also be used only as a last resort.

If enforced properly, such action would provide confidence in substances placed on the market and a fair competition among chemical companies on the EU market.

Background

Enforcement is a critical part of making REACH work in practice. It brings confidence in the safety of substances, mixtures and articles placed on the EU market. Proper enforcement of chemical legislation strengthens both the level playing field between EU and non-EU producers as well as protection of consumers and environment.

The EU chemical industry fully supports and encourages actions to accelerate the enforcement of REACH particularly for imported goods, including from online marketplaces.

In order to improve the quality of information provided by registrants in registration dossiers the European chemical industry [launched](#)¹ an unprecedented action in 2019 to help its members proactively and systematically review and update data in previously submitted REACH registration dossiers. The action is done in close cooperation with ECHA.

¹ Cefic REACH Dossier Improvement Action Plan: it is estimated that 7,170 REACH lead registrants' dossiers will have been reviewed by 2026 in the context of this Action Plan, representing one-third of all substances or more than half of all non-intermediate substances registered under REACH.

One of the actions proposed by the Chemicals Strategy for Sustainability (CSS) is to strengthen the principles of “no data, no market” under REACH, in particular by requiring compliance of all registration dossiers and revoking the registration numbers in case of non-compliance.

Currently, ECHA performs dossier evaluation checks to ensure compliance of all information provided. During this process, if the registrants fail to submit the required information, enforcement initiatives may follow: ECHA invites the national enforcement authority to consider actions towards the registrant. As a follow up to the enforcement action, registrants must provide a dossier update including the requested information to ECHA.

The new process, as announced in CSS, ensuring compliance checks on all registration dossiers, would apply at EU level (not only enforced/sanctioned in a (lead) registrants’ Member State).

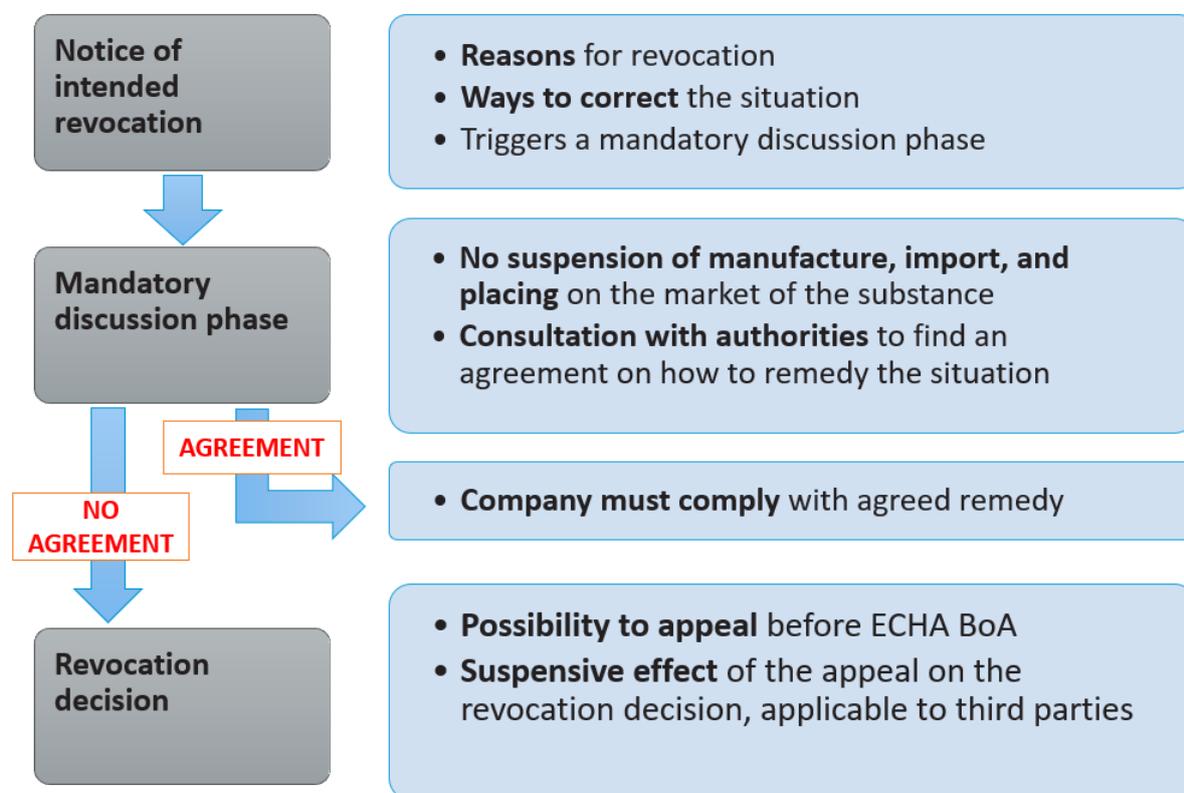
Cefic welcomes the introduction of a new (or updated) revocation process on registration numbers. We wish to highlight that a new mechanism of revoking non-compliant registration dossiers is a powerful tool and needs to include clear conditions, legal rights and due process.

Hence, we believe that the new system of revoking registration numbers needs to be based on the following principles:

- **Revocation as last resort.** Withdrawing a registration number is a powerful tool and should be considered as the last remedy.
- **Right to be notified and heard.** Companies should have the right to be informed and heard before a decision on revocation is taken as the ultimate remedy/last resort. The right to be informed could take the form of a notice of intended revocation specifying the reasons for revocation as well as possible ways to correct the situation.
- **Mandatory discussion phase.** Receipt of the notice of intended revocation would trigger a right to be heard in the form of a mandatory discussion phase with ECHA, during which companies would also be given the opportunity to consult with their national enforcement authorities on how to remedy the situation and find an agreement. During this “intermediate” step, the manufacture, import, and placing on the market of the concerned substance would not be suspended.
- **Possibility to appeal.** Companies should be able to appeal a revocation decision before the ECHA Board of Appeal. Such appeal should have a suspensive effect on the revocation decision, meaning new rules (revocation decision) would become effective only after the appeal procedure was concluded and in circumstances where the appeal outcome was in favour of ECHA. The suspensive effect should also benefit third parties², as they may rely on the registration dossier for their own compliance and would be impacted by a revocation decision.
- **No retroactive effect of revocation.** Revocation decisions should not have a retroactive effect as it should not impact past decisions. For downstream users, whether formulator or article producer, the registration number must remain a clear indication that a substance has been legally placed on the market before the revocation date.

² Co-registrants or other companies relying on data; Cefic notes that this is already a standard BoA practice in appeal proceedings for Substance Evaluation final decision where not all addressees appeal the decision.

Flow chart of Cefic proposal on revocation process in revised REACH text:



Situations to consider under dossier compliance

Cefic has mapped out preliminary situations where revocation of registration numbers may or may not be justified with non-exhaustive examples. These represent an early stage in the thinking process and Cefic welcomes further discussion on this with ECHA, the European Commission and other parties. These preliminary situations are provided by way of examples for discussion purposes only. In reality, each situation should be determined on a case-by-case basis according to its own circumstances.

Potential triggers for revocation of registration dossiers may include:

- **Non-compliant behaviour with empty dossiers and no changes.** It is crucial that the new legal provisions allow for a distinction between *intentional violations* by repeated offenders and *unintentional administrative errors or delays*.
- **No-longer existing registrant.** In cases where registrants continuously fail to reply within a given deadline, revoking a registration number is justified. However, substantial time should be given to the affected company via different communication channels.
- **Upon requests from registrants for their own dossier.** A registrant may ask ECHA to revoke their own registration number.

Cases where revocation may not be justified:

- **Co-registrants depending on lead-registrant's responsibilities.** In cases where the lead registrant is not responding or not fulfilling his/her obligations to update the dossier, co-registrant's dossier should not be subject to revocation. Instead, co-registrant should be able to alert their Member State Competent Authority or ECHA to act.
- **Administrative delays or technical difficulties caused by testing laboratories.** Revocation of registration dossiers should not happen in cases of justified delay with deadlines set by the authorities for which the registrant is not responsible. This includes cases where test results cannot be delivered because of non-availability of test slots, technical difficulties in the laboratories, necessity to repeat the test, or non-availability of test samples.
- **REACH IT issues.** ECHA's current and frequent technical changes in IUCLID (web based as well as the classic system) may have an impact on technical performance and companies' ability to update their respective registration dossiers on time; such delays caused by non-conformity with the latest IUCLID version should not trigger a revocation.
- **Disagreement on additional data.** There are situations when companies and authorities cannot agree if additional data are necessary during the evaluation process. Efforts should be made to facilitate agreement without that being an immediate trigger for revocation.

Cefic remains open to engage with the policy-makers, ECHA and other stakeholders to set clear criteria and legal process that would boost the EU level playing field and chemical safety for both human health and the environment.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production.