

REACH and CLP Hub: Dossier updates and enforcement

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Sini Suomela, head of REACHLaw's OR and registration practice, discusses dossier updates and enforcement.



Many companies have the impression that they can forget their REACH registrations after receiving the registration number. This is not the case. Companies have the responsibility to keep their registrations up to date and follow up on any changes. Updates can take place spontaneously but also through enforcement actions and/or request by Echa. REACH enforcement in 2019 will have a project targeting registrations and the quality of them.

Dossier updates

REACH [Article 22](#) places a mandatory requirement to update registration dossiers without undue delay if there are changes in the registration information. These include, but are not limited to:

- changes in company status;
- substance composition;
- tonnages;
- uses; and
- properties of the substance.

However, as these spontaneous updates are based on voluntary action, the vast majority of updates are triggered by Echa's own [regulatory activities](#), not by the registrants.

Companies lack incentives to update, even though it is a mandatory requirement, and there is a perception that "no additional work is needed" after the registration number is received. This means that new regulatory measures are definitely needed to ensure that companies update their REACH registration [dossiers](#) at fixed regular intervals, for example every three years as recommended by an expert group to Echa.

The recommendation would be best achieved through a "clarification or update" of Article 22, which might be feasibly done through an implementing regulation. Now, the situation is unfair as some companies are taking their responsibilities seriously and using time and resources for the update work, and some only start to act when an authority is pushing them. Lack of updates, of course, also pose a threat to chemical safety if the information in the registrations is not up to date.

Companies could also use up-to-date registrations as a marketing tool to show their customers that the company is taking chemical safety seriously and is regularly updating the registration information. Echa's dissemination tool nowadays shows which registrants have updated their dossier, showing a black dot (•) next to the name of those registrants that have updated their dossier at least once since registration, and displays a IUCLID symbol under the year of the latest dossier update.

'It is important to keep funds in a REACH budget to be prepared for future additional costs'

Some updates require only the lead registrant to update the dossier on behalf of all registrants and do not require co-registrants to submit an updated dossier to Echa. However, these updates still require cost sharing and they might lead to additional costs for all registrants. It is important to keep funds in a REACH budget to be prepared for future additional costs.

On the other hand, when letter of access costs are regularly recalculated, it is also possible that the registrants get refunds from the Sief. Another important part of the update work is to keep available resources for the required work. Time is needed of course for the submission of the update, but also often for answering different questions and even for testing. Hopefully, also REACH enforcement and inspectors will focus more on dossier updates in the future.

Enforcement

REACH enforcement is not the responsibility of [Echa](#) but of the national authorities in each member state. However, Echa coordinates the work of the Forum for Exchange of Information on Enforcement (Forum), a network of member-state authorities responsible for enforcement. The Forum has, for example, the following tasks:

- spread good enforcement practice;
- propose and coordinate harmonised enforcement projects;
- identify enforcement strategies, as well as best practice in enforcement;
- develop working methods and tools of use to local inspectors; and
- work together with industry to make enforcement as efficient and practical as possible.

In 2019, REACH registrations are a big focus point for the authorities. EU national enforcement authority inspectors will focus on registration obligations – including substances registered as intermediates – under the seventh REACH enforcement project (REACH-EN-FORCE-7).

They will check whether companies that needed to register substances on their own or in mixtures after the last registration deadline in May 2018 have a valid registration. In addition to checking full registrations, inspectors will examine intermediate registrations to see whether substances registered as intermediates fulfil the necessary requirements – that a substance is only manufactured and used under strictly controlled conditions. The inspectors will also work closely with custom authorities to ensure control of imported substances. The project will start its operational phase at the beginning of 2019 and run for one year. It will be followed by a one-year reporting period. Results are expected at the end of 2020.



Echa is, of course, also involved in enforcement activities as it has the power to withdraw registrations. One focus point in the last few years has been the Osor principle (one substance, one registration).

The Forum has pointed out that if breaches of obligations for joint submissions cannot be solved, Echa may revoke the registration if it fails the Osor principle. Echa will contact all registrants of the substance (outside and within the existing joint submission), remind them of their collective obligation to agree on the joint submission of data and set a deadline by which they need to find an agreement. If some registrants still breach the joint submission obligation, Echa may take regulatory action, including revoking registration decisions.

Echa is also trying to remove duplicate registrations from its records, including multiple joint submissions using the same EC number. In these cases, the two joint submissions can either combine (if the substance identity matches) or the other joint submission will receive a new EC name and number.

It is very important for non-EU manufacturers that have registered their substances through an Only Representative (OR) to remember that even though the OR is legally responsible for the registration and faces enforcement activities, a failed inspection or problems with the dossier quality will become a problem for the non-EU manufacturer also. In the worst case, the registration is withdrawn and supply to the EU market must stop.

'Companies who have registered substances must be ready for enforcement inspections at all times'

Companies who have registered substances must be ready for enforcement inspections at all times. There is no time to make dossiers compliant once the inspectors come, but everything

must be in order at all times. REACH compliance is a continuous effort, not a one-time exercise.

Summary

In general, it is always best to update registration dossiers as soon as new information becomes available. When the authorities or Echa request updates, there is only a limited time to submit the information. If a company has not been prepared at all for updates and, for example, needs to start finding service providers, compiling data etc, time might well run out.

REACH compliance doesn't mean only having a registration number. Every company should take responsibility for its data and not forget its REACH responsibilities, even though the registration deadlines have passed. If your company is being inspected by the national authorities, it is easier to show compliance when you know that your dossiers are up to date and you know that all the data is still valid.



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Further Information:

- [Echa REACH 2018 web page](#)
- [REACH Article 22](#)

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