

Constantly keeping your REACH dossiers up-to-date: this is NOT a 'nice-to-have legal option'

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With the completion of the third and last REACH registration deadline in May 2018, ECHA and several other REACH stakeholders have quickly moved their focus to dossier quality, demanding clear dossier quality improvement from industry. While the regulation obliges all registrants to regularly update their dossiers with relevant new information, fact is that 64% of the dossiers have never been updated since initial submission, which dates back to 2008 for substances with ≥ 1000 tpa! To address the concern and to pre-empt a potential binding regulation on dossier update requirements, Cefic urges its members to develop a plan for systematic dossier reviews and updates, considering this as a key issue for industry.

Several important events all together point to the same conclusion that industry needs to take regular dossier updating much more seriously than until now.

- ECHA implemented several changes to the dossier evaluation and compliance check process, effective since 1 January 2019. From now on, members' dossiers are no longer excluded from checks for composition consistency across the joint submission. Partial or full opt-out dossiers will be assessed in parallel with the data submitted jointly. Once a draft decision is issued, it will no longer be possible to change e.g. the tonnage band, the type of registration (full vs. intermediate), or the uses. **ECHA is clearly expecting dossiers to be up-to-date and it will not inform registrants or grant a chance for dossier updates prior to regulatory measures.**
- More of the same: the European Commission published a document regarding the scope of an Implementing Regulation on registration updates, proposing fixed timeframes for the relevant change triggers. After collection of stakeholder input, it plans to present a proposal to the REACH Committee in February 2019, so that voting may take place as early as in April 2019. Just as an example: the draft document recommends an at least yearly review of quantities. **If approved, such an Implementing Regulation would impose strict binding requirements for dossier reviews and updates.**
- The BfR (German federal institute for risk assessment) published a widely noticed report on their assessment of dossier quality in which they stated that rather high percentages of the 500+ assessed dossiers were deemed "not compliant". While the applied methodology

was very specific and differed from the official Compliance Check process as REACH Art. 41, the publication triggered enormous attention in the press and media. It was used by the German Government as a reason to demand significantly higher percentages of dossiers to undergo the Evaluation process than the formally required 5% of all dossiers. **Government officials outlined their position to have all (100%) of the dossiers being evaluated in the next 10 years.**

- On 21 December 2018, Cefic reached out to its members highlighting the urgent need for industry to respond to the pressure for higher dossier quality. As part of its immediate actions, Cefic representatives will meet with ECHA leadership in an informal meeting at the end of January 2019 to understand their views on the improvement priorities. Cefic also issued a checklist by which companies are guided in their internal assessment of dossier quality. This is definitely a proactive step in order to avoid far-reaching new regulatory obligations. **Join the initiative and ensure your dossiers are up to the expected level of quality and compliance!**
- On 9 January 2019, ECHA informed the public about upcoming EU/EEA inspections for compliance with REACH registration obligations. The initiative in which both inspectors and customs authorities will be involved is part of an EU-wide Forum* enforcement project (called REF-7). The project aims to verify REACH compliance for the obligations of manufacturers and importers. The checks will cover substances in all tonnage bands. **The inspections will also include a check of parts of the registration dossier and of other duties related to registration, e.g., whether the registrant is compliant with the duty to update a registration dossier.**

*The Forum for Exchange of Information on Enforcement (Forum) is a network of authorities responsible for the enforcement of the REACH and other chemicals related regulations in the EU and the EEA countries.

In the light of these circumstances, SCC strongly recommends a dossier update program to its clients in order for them to stay ahead of the foreseeable changes in the regulatory environment. We already set up such systematic projects for a number of mostly bigger internationally acting companies.

What is your plan for keeping your REACH dossiers up-to-date? Please come and talk to us if you want to enhance your ability to stay agile and to ensure compliance for your chemicals in Europe!

For more information, please contact SCC at scc@scc-gmbh.de – thank you.