

Nearly half of medium tonnage REACH dossiers possibly 'non-compliant'

But results of German government project suggest better 'compliant' rate than high tonnage band

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Nearly half of all REACH dossiers in the medium – 100-1,000 tonnes per annum (tpa) – tonnage band could be non-compliant with respect to ecotoxicity, according to analysis by a German government project.

In the analysis, compliance is not defined with reference to law, but by criteria developed within the project, and the conclusions relate specifically to compliance in terms of a particular hazard endpoint, not the overall dossier.

Furthermore, there are some indications that, in general, compliance for this band may be better than for the 'high' – 1,000tpa or more – tonnage band, which the project previously analysed.

Nevertheless, NGO the European Environmental Bureau (EEB) says that the results confirm the level of compliance with REACH is generally low.

The current analysis was performed by the German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA) as part of their joint REACH Compliance project.

Echa provided data on 2,053 lead and individual registration dossiers in the medium tonnage band submitted by March 2017. The full set of dossiers went through 'screening' checks, while a randomly selected subset of 500 also went through 'formal' and 'refined' checks.

Throughout, the team considered eight endpoints. Combining the analysis for all three checks for the subset of 500 dossiers showed that the ecotoxicity section was "non-compliant" in 46% of cases. The non-compliant proportion was lower for the other endpoints, such as reproductive toxicity – with just 9% of cases being 'non-compliant'.

Averaging across the endpoints, 45% of the cases were "compliant". The equivalent proportion for the high tonnage band was 34%, obtained during previous analysis. These



proportions give an indication of compliance in general but are not meaningful at the dossier level because a single dossier may be non-compliant in relation to multiple endpoints.

Nevertheless, they suggest that, broadly, compliance for the medium tonnage band may be better than for the high tonnage band.

In general, the team found that standard guideline studies were available in only a "limited" number of endpoint entries, while data waiving and adaptation had been "intensively used".

To address data gaps arising from a lack of standard information or an insufficiently established data waiving or adaptation approach, registrants should "thoroughly review" their dossiers and improve the data if necessary, the team said.

Reaction

Cefic said it agrees with the project's observation that some dossiers should be revised to bring their testing strategies in line with Echa's current requirements.

The trade body has a cooperation [agreement](#) with Echa to develop more case studies and examples of alternative approaches as part of a broader voluntary action plan to improve dossiers. It is conducting a pilot project and will

publish a document outlining the most effective testing strategies.

Meanwhile Tatiana Santos, policy manager at NGO EEB, said the project results were in line with Echa's latest [statistics](#), which highlight recurring issues with the quality of data in dossiers.

"We are not seeing much activity from national authorities to address the issue," she added.

Echa and the Commission have a joint action plan to [tackle](#) the issue, but they should look "deeply into the source of the problem" and address the industry's conflict of interest.

REACH Compliance project

The current analysis is part three of the REACH Compliance project, which the UBA and the BfR launched in 2014 to determine the availability and quality of human health and environmental risk data submitted under REACH.

The project team published part one, on screening of the high tonnage band dossiers, in 2015, and part two, on more detailed analysis of the same dossiers, in [2018](#). The latter caused a furore among member states and NGOs over widespread compliance failures, and led to action from Echa and the European Commission.

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