AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Improving REACH in 2018 and beyond

Regulators' criticism of poor quality Registration dossiers

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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AmCham EU recommendations on how to improve REACH in 2018 and beyond

Regulators' criticism of poor quality Registration dossiers

Increased efforts from authorities to improve the registration process

ECHA and Member States have long complained about the quality of submitted registration dossiers. As a result, the number of checks (e.g. mass IT screening) performed have increased significantly. Additional features have been added to the regulatory software (IUCLID quality assistant) to ensure that high quality standards are met. Moreover, ECHA started sending targeted letters requesting registrants to improve and update their registration dossiers.

Members of the American Chamber of Commerce to the European Union (AmCham EU) recognise ECHA's efforts in the last few years. This included educating registrants and providing additional tools and guidance documents to improve the quality of the dossiers that are submitted. In particular, the help pages on the ECHA website and the quality assistant tool are valuable resources.

Good quality data and dossiers are essential for authorities to evaluate the risks posed by the use of chemicals and to take appropriate regulatory decisions. However, the requests made by the EU authorities and Member States often fail the proportionality test and may not be entirely justified, making them extremely burdensome for industry.

Reasons why dossiers don't meet quality expectations

To improve the quality of the dossiers submitted to ECHA, we first need to understand the reasons why many dossiers do not meet the quality expectations:

- REACH is an extremely complex piece of legislation and companies had little time to prepare for the first wave of registrations in 2010. Guidance documents were produced late and kept changing over time.
- Companies are currently busy preparing for the next registration deadline and therefore are unlikely to have many resources available for spontaneous updates. In addition, we believe that ECHA should consider a moratorium on new mass compliance checks until the next registration deadline, as companies cannot cope with the current amount of work.

- IUCLID, REACH IT and the completeness check tool have been updated several times. This requires constant training of staff and makes small updates very cumbersome since even a minor change may cause a major revision of the whole dossier.

- ECHA's expectations are sometimes too high. This is especially the case for substance identity, where the Agency's approach is often too academic. Occasionally, ECHA even requests registrants to change the name of a substance, or split the registration in two or more separate submissions, with no practical advantage being gained. Such requests trigger

an enormous amount of work and create confusion both on the market and in the supply chain.

- There is a great deal of confusion regarding animal testing. On one hand registrants are supposed to explore alternative testing strategies and use vertebrate testing only as a last resort. On the other, ECHA is very reluctant to accept non-animal testing alternatives. For these reasons the Board of Appeal has been called to settle disputes several times. More clarity on when testing is absolutely necessary and when alternative methods are instead acceptable would be welcome.

Recommendations

Fixed interval dossier updates are counterproductive

Art. 22 of REACH makes the update of dossiers compulsory when certain changes occur or new information becomes available. However, ECHA recently published a report in which it calls for a review of this Article by making the rules clearer and by introducing the obligation for updating the dossiers at fixed intervals. We welcome the clarifications, however, requesting companies to update dossiers at regular intervals would be burdensome, unnecessary and counterproductive.

Manual checks go beyond their scope

Another issue often flagged by industry is the introduction manual checks of the submitted dossiers. We understand that this step was introduced to prevent companies from submitting incomplete dossiers which were able to pass the automated check but that did not contain meaningful information (e.g. a dossier with a 'study in progress' type of statement instead of actual endpoint data). However, we noticed that in some cases the manual check goes beyond the stated purpose of verifying the completeness, as some dossiers are rejected on the grounds of the validity of certain waiving arguments. We think this is something that should be tackled by the compliance check process rather than by the initial completeness check as it requires an in-depth scientific assessment.

Accepting inquiry-supplied substance identifiers would reduce lags

Also, after the 2018 deadline, with the elimination of the Substance Information Exchange Forums (SIEFs), any new registrant will have to submit an inquiry dossier before the registration. This means that several months would pass from the date in which the registrant decides to import or manufacture a given substance and when they can actually do it. ECHA should consider adopting a mechanism aimed at reducing this lag as it can seriously harm competitiveness and business opportunities. A possibility would be to provisionally accept the substance identifiers supplied with the inquiry pending its review. The registrant would be then able to contact the lead registrant and start the preparation of the dossier without waiting the several weeks that normally take to review the inquiry documentation.

Enforcement should apply to poorest quality registration dossiers

Enforcement also should apply to the poorest quality registrations dossier (such a threshold should be defined.) AmCham EU members are well aware of the regulators' criticism of poor registration

dossier quality, however representing companies which have sought to comply with the sizeable efforts of registration and have endeavoured to do this well, there is frustration in not being told what quality means and how to improve it.

This will be essential in the REACH world after the June 2018 registration deadline. In addition to this clear guidance, we also believe that the poorest quality dossiers should be sanctioned. AmCham EU members are familiar enough with the stakeholders of the REACH world, including of ORs and consultants who works on reach dossiers, to know that a number of them have a reputation for poor work. We assume that ECHA is also familiar with those actors, and a targeted screening of these dossiers, which are often linked to importers from Asia should be given specific scrutiny, instead of all registrants being treated in the same way.