

EEB Comments to Doc. CA/59/2018. Second REACH Review Action N° 1: Encourage updating of registration dossiers

The EEB welcomes the measures proposed by the Commission and by ECHA in this document to improve the quality of registration dossiers, however we believe they lack of ambition and that further stronger measures are needed to solve the problem of non compliance.

Poor quality and non compliance of dossiers is a very serious matter. According to the ombudsman the main problem *is the systemic shortcoming in terms of a lack of incentives for registrants to update their files, despite an obligation to do so.* In fact, there are too many incentives for non compliance, such as the lack of regulatory action, the low chance that a dossier will be evaluated, the lengthy of the process and the softness of enforcement. From a company's perspective, it is "worth" not to comply and "wait and see".

Enforcement, transparency and market access are the best incentives for compliance.

Further measures to ensure REACH enforcement are needed, such as:

- ECHA should not grant registration numbers for non compliant registration dossiers, for example, for empty dossiers or dossiers with inadequate information, such as insufficient description of a substance identity. More manually examined dossiers and fewer automated completeness checks, that don't evaluate how adequate the information is, are needed.
- Withdraw the registration of non compliant dossiers (enforcement of Art. 5) in order to ensure a level playing field that favours companies taking REACH seriously. Although ECHA agreed it may invalidate registration numbers in well-justified cases a few years ago, revocation has only been considered in cases where registration numbers were assigned to non-existent registrants, and where they failed to pay the correct registration fee. However, there are some "good cases", such as the Board of Appeal case where an almost empty dossier was accepted by ECHA (Case 22/2013)¹;
- Ensure mandatory updating of registration dossiers (enforcement of Art 22.1)
- Initiate regulatory actions for substances with bad quality registration dossiers, such as prioritisation for evaluations and restrictions.
- Avoid the misuse of non animal testing methods (enforcement of Art 5) by considering
 dossiers that misuse non animal testing methods and non-compliant data waiving and
 initiating regulatory actions or withdraw registration numbers.

https://echa.europa.eu/documents/10162/56569ebe-dc6f-4831-aa72-6cc4819293ee

Improve REACH implementation and REACH Regulation

The EEB recommends the EU authorities to:

- Increase the number of compliance checks and extend compliance checks to chemical safety reports.
- Address the use (and misuse) of data waiving and on animal test methods.
 Incorrect data waiving is the reason for non compliance of most of the registrations dossiers. Misuse of animal testing is hindering the identification of SVHC and therefore hindering the protection of human health and the environment.
- Ensure all scientific evidence not captured by standard testing methods is used.
- As the REACH Review Staff Working Document recognises, REACH is not generating relevant and specific information for nano forms of substances, ensuring the identification of endocrine disrupting properties and addressing the combination effects of chemicals.
 Specific measures are needed to integrate scientific developments into REACH.
- Bring low-volume production substances and polymers into the REACH regulation

Improve transparency on registration dossiers

Transparency is a very good incentive to compliance as both market access and reputation are very important for companies. Moreover, it would ensure informed decisions by citizens, increase market pressure and protect human health and environment. Measures to increase transparency include:

- Name/Fame and Shame:
 Name of compliant & non-compliant companies
 Traffic light system for dossiers regarding quality
 For which dossiers is safety proven/not proven?
- Publish date of dossier updates and which data have been updated
- Publish Chemical Safety Reports
- Allow third party public submissions/comments on missing and new information in registration dossiers. This will allow academia and independent scientists to participate in the improvement of the information of the dossiers and would help registrants to complete, correct and update their dossiers.