EEB comments on Revision of REACH - Evaluation (CA44, AP 4.1)

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Introduction

The EEB welcomes the proposals presented by the Commission for the revision of Evaluation and Registration under REACH. These proposals are essential to achieving the objectives of the EU Green Deal and the accompanying Chemicals Strategy for Sustainability Towards a Toxic-Free Environment.

Registration and evaluation are the pillars on which hazard identification and subsequent risk management measures are built under REACH, including the phase-out of substances of very high concern. However, today the high level of non-compliance of the registration dossiers is a major bottleneck in the implementation of REACH as it overloads the evaluation process and drains ECHA resources. It is the cause for delays in hazard identification and the implementation of risk management measures, leaving people and the environment exposed to potentially toxic chemicals for many years.

The process for registering substances under REACH and obtaining the licence to place chemicals on the EU market takes only 3 weeks, while it takes over a decade[1] for authorities to take them off the market again. The European Court of Auditors[2] recognised the problem of the wide occurrence of non-compliant chemicals on the market and concluded that after the company receives a REACH registration number allowing it to market its chemicals, "it can keep this registration number even if it is subsequently shown to have provided incorrect or incomplete information. This arrangement reduces the company's incentive to provide updates or additional information".

[1] EEB's unpublished analysis

[2] EU Court of Auditors report

- To overcome these problems, implementation of the proposals presented by the Commission for the revision of registration and evaluation will be a prerequisite for a successful revision of REACH. We highlight our main recommendations in this document following the discussions at the Caracal meetings in March (Ad Hoc CARACAL meeting and CARACAL44 meeting). Our detailed comments can be found here.

Recommendations

1. **Strengthen the No data - No Market principle**. Currently the REACH legal text states that "The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted" (Article 20.2). This has led to allowing substances on the market with incomplete dossiers, for which it is not known whether they are safe. ECHA should be allowed to assess the adequacy and reliability of the data submitted at the time of registration. Registration should be rejected in case dossiers are clearly not compliant with the legal standard information requirements. This will also allow for the early identification of dossiers that are of priority for further evaluation, hazard identification and risk management measures.
2. **Implement dossier expiration date**. It is the registrants' responsibility to keep dossiers up-to-date, however the current provisions in REACH are not sufficient to ensure regular updates. Currently the registration is a licence to market without an end date. This arrangement reduces the registrants' incentives to provide updates or additional information and consequently many dossiers were never updated since their first registration in 2010. Therefore, an expiry date should be assigned to the registration decision, which reinforces the accountability of the registrants for keeping their dossiers up-to-date. Failure to update dossier by expiry date should lead to automatic revocation of registration number.
3. **Introduce a mandatory requirement for annual reporting of general information on manufacture and uses of the substances.** Data on production volumes and use patterns (consumer use, wide dispersive use) is crucial for the priority setting of substances for evaluation, hazard identification and risk management. This information should be up-to-date at all times to allow for meaningful and efficient priority setting and risk management. Furthermore, this information will provide insight into trends in market volumes, e.g. to keep an eye on substitution of SVHC.

4. **Empower ECHA to revoke registration numbers**. The current legal text allows ECHA to grant registration numbers, but it does not allow the agency to revoke registration numbers and the registrant keeps its licence to market, even if it is subsequently shown to have provided incorrect or incomplete information. Therefore, ECHA should be empowered to revoke registration decisions in case of absence of updates, failure to comply with legal information requirements, failure to comply with evaluation decisions, etc. The zero-tolerance approach to non-compliance as committed in the CCS is needed to ensure that EU market access is not allowed in case safety is not demonstrated.

5. **Make registrants accountable for costs inherent to non-compliant dossiers**:

   As many substances are on the market with non-compliant dossiers, for which safety has not been demonstrated, it is unclear whether they are harmful or not. Companies should be held responsible retrospectively for the damage caused by keeping non-compliant dossiers on the market, e.g. in case of reprotoxic effects. In addition, fees should be introduced for the costs associated with the resources spent by authorities to handle non-compliant dossiers.

6. **Speed-up and simplify the evaluation process**:

   - Introduce flexibility and allow for simultaneous dossier evaluation and substance evaluation. We believe that this will ensure a faster generation of the information needed for hazard identification and risk management.
   - Introduce a legal framework that allows evaluation and testing strategies based on group considerations to maximise the effectiveness of the evaluation procedure as well as to prevent regrettable substitution and reduce vertebrate testing.
   - Shorten the decision-making process and establish deadlines for every step in REACH articles 51 and 52. The current time frame of 12 months for issuing draft compliance check decisions should be shortened, and a final decision for data generation should be adopted within one year from the start of the evaluation. The comments provided by registrants should be limited to a maximum text size and two a maximum of two possibilities to comment. We note the efficiency gains over the last years in decision making avoiding repetitive discussions, and value the MSC involvement in the process.

- Introduce a maximum deadline by which the evaluation process needs to be completed and the dossiers need to be compliant. Revoke registration number if deadline is not met.
- Introduce a deadline for risk management follow-up of SEv and CCh in case of conclusions of concern. If substance evaluation conclusions confirm that the substance is of concern, the recommended follow-steps for hazard identification or risk management should start immediately and deliver within clear deadlines and REACH should specify the responsible actors.