Action 7: Ensure a continuous dialogue between the industry and ECHA during the dossier evaluation process

The Issue?

The REACH Regulation is a cornerstone of the EU's chemicals policy, ensuring a high level of protection for human health and the environment. A key requirement for all European companies is to register a substance with the European Chemicals Agency (ECHA) in order to place it on the market. ECHA evaluates the dossier to ensure compliance with the registration requirements. This could result in the Agency asking for additional data. However, industry stakeholders, particularly small and medium-sized Enterprises (SMEs), encounter considerable challenges when faced with such a request:

Limited Interaction with ECHA

Currently, the REACH framework only foresees a possibility for industry to provide written comments towards the end of the evaluation process. The absence of direct interaction between ECHA and companies during key stages of the dossier evaluation process, particularly when regulatory decisions are unclear, leads to inefficiencies, misunderstandings, and delays. While the industry can submit written comments, the lack of ongoing dialogue means that issues may not be fully clarified early in the process, often leading to unnecessary complications in compliance. In addition, while REACH provides an opportunity to provide data without using animal testing (so called "adaptations under Annex XI"), the lack of a dialogue has often resulted in companies having to perform animal testing, while REACH requires to perform animal testing only as a last resort. This point is explained in factsheet on Action 9.

Fragmented feedback process

The existing feedback channels, such as the ECHA Helpdesk, are reactive, addressing specific questions but not enabling discussions. The absence of a structured, ongoing conversation with ECHA on testing proposals, compliance checks, and hazard classifications often leads to misinterpretation of ECHA's requests by industry and misalignment of expectations between what ECHA requests and what the industry needs to provide.

Lack of dialogue makes a lengthy data generation process even more complex.

Generating (eco)toxicity data necessary for REACH registration dossiers can take several years, being up to 3-4 years for complex studies, and requires a number of decisions to be taken by sponsors and laboratories, like Contract Research Organisations (CROs). Having discussions with ECHA experts could readily reduce uncertainty around particular information required for specific dossiers, e.g. concerning study design, and even allow for increased streamlining during study performance.

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The Solution

Fostering aligned expectations and a structured discussion

To address these concerns, we propose to establish communication channels that foster continuous, open discussions between the industry and ECHA, ensuring clearer expectations, tailor-made data generation, the use of animal testing truly as a last resort, and more efficient dossier evaluations.

This channel would serve as a mechanism for discussing issues related to dossier evaluation, testing proposals, data requests, adaptation strategies based on science and other regulatory matters. The core objective is to ensure that all parties are aligned on expectations and regulatory requirements.

Following the approach of other regions, we see the value of regulatory frameworks that promote direct and continuous communication with industry stakeholders, leading to a smoother compliance process. Examples of such frameworks include the US Toxic Substances Control Act (TSCA), Japan's Chemical Substances Control Law (CSCL) and Canada's Environmental Protection Act (CEPA).

How It Works

- Industry representatives would be able to initiate discussions with ECHA on specific technical issues and data requirements.
- Registrants would be able to have one-on-one discussions with ECHA experts.
- ECHA would clarify regulatory and/or scientific expectations, allowing the industry to adjust or refine its dossiers before submitting them formally.
- The communication channels would focus on clarifications, alignment of understanding, and exchanging relevant new information—not on legal advice, as compliance remains the responsibility of the industry.

Benefits of the Continuous Dialogue

- **Increased efficiency:** Clearer expectations from the start would reduce delays in the evaluation process, allowing for faster safety data generation and quicker dossier submissions.
- **Improved transparency:** Facilitating open communication would ensure that both the industry and ECHA are aligned on regulatory actions, expectations, preventing misunderstandings that may arise during the formal dossier evaluation process.
- **Enhanced industry participation:** Particularly for SMEs, the communication channels would lower the barriers to participation, providing them with a straightforward way to clarify regulatory requirements and avoid costly mistakes.
- **Using animal testing as a last resort:** Fostering continuous dialogue between industry and ECHA would ensure that animal testing is truly a last resort. By enabling proactive discussions on non-animal strategies for meeting regulatory requirements, the communication channels would increase transparency in applying adaptations, promote the use of advanced scientific methods, and support capacity building within ECHA and the industry. This approach aligns with the EU's broader goals of advancing sustainability, reducing animal testing, and improving the efficiency of chemical safety assessments.

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- **Streamlined decision-making:** Early alignment would lead to more efficient decision-making processes, reducing cases requiring intervention through formal appeal procedures.
- **Learning from past experiences:** The communication channels would allow ECHA and the industry to learn from past interactions, refining testing and data evaluation approaches.
- **Cross-cutting discussions:** The communication channels could also identify where multiple stakeholders face similar challenges, such as difficulties with testing certain substances, challenges with dose-setting, or concerns around using information on exposure. This would allow cross-cutting discussions on these issues, fostering more targeted regulatory actions.

Practical considerations:

- To prevent the communication channels from becoming overwhelmed, it will be essential to implement clear guidelines for its use, ensuring that discussions focus only on regulatory uncertainties not already covered by existing guidance documents.
- The ECHA Helpdesk would act as the gatekeeper for the communication channels, ensuring that only relevant, well-defined requests are submitted for discussion.
- ECHA's involvement would remain focused on providing clarity and not on giving legal advice, ensuring that the industry remains responsible for its own regulatory compliance.

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