



EEB and CHEMTrust comments on the proposal to establish a Subgroup on Test Methods under CARACAL

CARACAL 52, Joint REACH - CLP session, AP 4.a

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Introduction

We welcome the Council's conclusions¹, emphasizing “the necessity of sound testing methods to identify possible negative impacts of exposure to chemical substances and establish legislation to guarantee safe use of chemicals on several types of toxicological characteristics...”

The availability of adequate and validated test methods is crucial for an effective implementation of the REACH and CLP regulations as well as for other EU laws. However, the current delays in the development and updating of test methods hinder the ability to identify and regulate harmful chemicals in a timely and precautionary manner. Accelerating the regulatory uptake of new and updated test methods is critical for regulatory risk management intending to protect human health and the environment.

We, therefore, also see the need to review and update test methods for regulatory uptake and use as described in the documents presented to CARACAL by DE/NL. The aim should be to ensure the latest scientific developments from EU research projects and other relevant scientific projects are integrated and applied for an effective implementation of the REACH and CLP regulations as well as other relevant EU regulations.

For this, a dedicated expert group with the task to discuss prioritisation and validation of methods to detect specific endpoints, building on the expertise from ongoing work by e.g. PARC, and linking with the activities under OECD would be very useful. However, this can only lead to meaningful progress if the necessary funding for validation is addressed.

¹ Council of the European Union. The 8th Environment Action Programme Mid-term Review - The way forward to a green, just and inclusive transition for a sustainable Europe - Council conclusions (ST 11326 2024 COR 1). 17 June 2024. <https://data.consilium.europa.eu/doc/document/ST-11326-2024-INIT/en/pdf>

Key points for consideration

1. **Prioritisation of test method development and funding of validation:** It is essential to prioritise the update, development and validation of test methods that have direct regulatory relevance, particularly those aligned with CLP criteria or necessary for REACH SVHC identification. The current obstacle of funding validation processes must be addressed. The test methods must stand legal scrutiny.
2. **Addressing data gaps:** Test methods must be developed to address current data gaps in the standard REACH information requirements, especially for endpoints such as endocrine disruption, immunotoxicity, neurotoxicity and transgenerational effects. Many promising methods have been developed under the EURION research initiative; some will be taken forward in the context of the OECD and continued under PARC. In addition, there needs to be a space where the potential regulatory use of new promising methods can be assessed in a systematic way with the aim of closing existing gaps and prioritising them for validation.
3. **Building on existing expertise:** Numerous activities are already taking place across various platforms, such as PARC, ECVAM, PEPPER, and EURION. More transparency is needed to share the various efforts and outcomes of these initiatives. A new expert group could bridge these research forums and incorporate the regulators perspective.
4. **Encouraging uptake of academic data for regulatory purposes:** Academic research often provides valuable insights and innovative methodologies that can enhance regulatory decision-making. Establishing guidelines for integrating academic findings reported in other formats into the regulatory process will help bridging the gap.
5. **Replacing time-consuming methods:** We support looking for the replacement of time-consuming methods with new approach methodologies that are faster and more efficient, reduce the use of animals, as well as accelerate the protection of human health and the environment from harmful chemicals.
6. **Informing the Commission work towards phasing out animal testing:** The work of such a new expert group could also inform the ongoing Commission work on the roadmap towards phasing out animal testing for chemical safety assessments. Input from the authorities' risk assessors perspective is essential for developing this roadmap.

Conclusion

We agree on the importance of speeding up the prioritisation and validation of methods for regulatory use. We therefore support creating a space for the necessary scientific discussions from a regulatory perspective and taking into account the existing expertise from ongoing projects in e.g. JRC, PARC and Pepper. The current obstacle of funding of validation needs to be addressed. Swift regulatory uptake of relevant methods to speed up identification of (groups of) substances should be prioritised. No matter whether a new or existing group is used for this task, CARACAL should be closely involved in the work to ensure regulatory relevance and increase transparency of the various discussions going on in different fora.