7th August 2025

Written comments as follow-up to the 3rd EU Commission workshop on the development of a roadmap towards phasing out animal testing for chemical safety assessments

Following the discussions at the EU Commission workshop held at the EU Chemicals Agency in Helsinki on 16th and 17th June 2025, our organisations would like to provide the European Commission (EC) with some comments for input to the final development of the roadmap. We are building on our responses to the public consultations and surveys. We also note that we are concerned that the process seems to lack the proper involvement from EU Member States as well as independent scientists. This aspect also came up in the discussions in June in Helsinki.

Disclaimer: Our comments mainly aim to provide input on some of the key elements of the roadmap as presented in Helsinki. We are not making recommendations on the use of new approach methodologies (NAMs) in specific pieces of EU legislation.

General comments

As the EC enters the final drafting phase of the EU roadmap to phase out animal testing in chemical safety assessment, we would like to provide some key considerations.

The 2020 EU Chemicals Strategy for Sustainability (CSS) has rightly described the need to strengthen the chemical science-policy interface: ***Safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency, and speed of chemical hazard and risk assessments (CCS, page 22).***

In this context, we welcome the discussion on the preparation of the Commission roadmap. We have contributed to previous consultations and we are making the comments below on the main elements that were presented at the 3rd Commission workshop in Helsinki in June 2025.

Our main comment is that the protection of human health and the environment should have a central role in the roadmap. Protection needs to be improved not only from chemicals that are already in use, but also for the ones that are under development. The procedures should be independent, transparent and objective. It is therefore, essential to have a careful balance between the involvement/representation from regulators, civil society and industry. Conflict of interest should not interfere with the process of increasing protection from dangerous chemicals and phasing out animal testing. Identifying properly the toxicity of chemicals during the regulatory hazard assessment is crucial because if a chemical turns out to be toxic after it has been placed on the market, it may take years to get it removed, while the harm to people and wildlife cannot be undone.

Specific recommendations

1.) **Ensure that the EC roadmap will improve and speed up hazard identification and enhance protection.**

The roadmap should put the focus on better and quicker predictions of harmful effects with NAMs. While many methodologies still need to be developed, some available tools seem promising. In particular, read-across and grouping, if done properly, have a large potential to speed up assessments, flag harmful properties and act as a basis for risk management. Currently, EU citizens and ecosystems are already exposed to hundreds of chemicals from multiple sources and with incomplete/unknown or unreliable hazard data and to many which are suspected to be harmful.[1] The consequences of overlooking harmful properties or potential misuse of tools to declare safety based on insufficient information need to be considered and addressed.

2.) **Introduce indicators suitable for measuring transition to NAMs and regulatory use.**

We recommend using a suite of indicators that are able to map progress in regulatory decision making, reducing the burden on authorities and speeding up the processes. It would also be useful to subject the indicators to a periodic review.

The roadmap indicators should:

- Reflect the EU protection goals for human health and the environment.
- Focus on all three Rs: replacement, reduction and refinement.
- Include progress from more integrated approaches to make use of all data (see e.g. EU research project ERGO[2] combining human & environment assessment for EDCs). Certain methods, including more application of read-across to predict toxicity, can already be applied to improve assessments, whereas others will take more time. See also results from other EURION cluster projects.[3]
- Reflect the regulatory use of NAMs in the implementation of the CLP regulation, such as progress in identifying the toxicity of chemicals and predicting the adverse effects they may induce, without producing evidence of these adverse effects from animal studies (e.g. the number of substances that are classified based on NAMs; the number of self-classifications by companies identifying hazards based on NAMs). This should cover both category 2 and category 1 classification (e.g. for CMRs and EDCs), as much of the risk management legislation so far only covers category 1.
- Plan for advancing grouping approaches in potential future classification and risk management as means to reduce animal testing, always without weakening precautions to protect human and environmental health.

[1] Commission Staff Working Document on progress report on the assessment and management of combined exposures to multiple chemicals and associated risks, 2020
[2] https://ergo-project.eu/
[3] https://eurion-cluster.eu/

3) Strengthen synergies for validation, link to envisaged EU testing and validation strategy.

- Correct validation is essential to avoid that the methodologies established fail to predict properly the toxicity of chemicals. This would result in lowering rather than increasing the level of protection.
- Validation needs to be based on well-defined criteria. Validation criteria need to be science-based, defined transparently and agreed in advance. Although several tests have been developed by the scientific community, it`s clear that we need more *in vitro* to *in vivo* extrapolation models and more predictive methods – but the prioritization and funding has to be agreed upon and decided at a policy level.
- Sufficient funding mechanisms are needed to accelerate validation processes. This has been recognised at the OECD[4] and also been discussed at the Amsterdam workshop in January 2025, hosted by the Dutch Ministry of Environment.[5] The roadmap should establish close links to these processes.
- It is essential to prioritise the update, development, standardization and validation of test methods that have direct regulatory relevance, such as for substances used in low volumes under REACH, and also for use under CLP.
- The roadmap should propose a mechanism to develop a regulatory approach that takes action based on early warnings rather than waiting for proven harm in multiple animal studies. This means that newly developed methods must be acceptable for classification in the EU regulatory system.[6]
- Methods striving for validation (laboratory-based and computational) need to be transparent and available for public scrutiny.
- Method development with the aim of future validation requires improved communication between scientists and regulators in the context of EU research projects, as was also discussed in Helsinki. Academic researchers need to be aware about the minimum reporting requirements to enhance the acceptability of their publications for validation and regulatory purposes. It would also be good to facilitate the accessibility of research data (e.g. as part of a NAMs database).
- Attention should be given to the likelihood and management of false-negative and false-positive results in a certain method, as well as other limitations regarding e.g. a method's predictive value, applicability domains, specificity, etc.

4) **Build on existing structures and EU research networks**

- The implementation of the roadmap will require joint efforts and the experience from many stakeholders. It is therefore important to build on available expertise and avoid duplication of existing structures.
- Each suggested group in the newly proposed roadmap structure needs a clear scope and dedicated tasks. There needs to be transparency on membership, including on potential conflict of interests.

[4] https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/09/workshop-report-on-operational-and-financial-aspects-of-validation_639a6ff7/db9979eb-en.pdf
[5] https://bureau-reach.publiqa.online/policy-conference-european-test-method-validation-strategy/chairmans-report
[6] https://chemtrust.org/stronger-reach-alternative-methods/

- Including relevant expertise will be key for success, in particular regulators and independent academic researchers who have not sufficiently been involved in the development process of the roadmap so far (as was expressed during the Helsinki workshop).
- Make use of the EU research findings from e.g. Merlon[7] and PARC[8], who are developing tools and have highlighted test method development needs for various endpoints.

Conclusion

Hazardous chemicals can jeopardize the ecosystem resilience, leading to rapid declines in animal populations and, ultimately, to extinctions, as well as severely impacting human health and wellbeing (CCS, page 13). As highlighted in a joint NGO letter signed by 22 organisations in 2023, the transition to non-animal testing needs to go hand with hand with improved protection of people and the environment from harmful chemicals.[9]

The Roadmap provides the opportunity to build a system to move away from testing each individual substance with animal tests and still be able to identify and classify their hazards and take appropriate regulatory action. At the same time it's crucial to prevent lowering the protection of human and environmental health. For instance, regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain, requires that only regulatory studies that have been notified in advance will be accepted by the authorities, thereby avoiding that multiple testing is performed. This can serve as an example for how to prevent the abuse of false negative results.

It needs to be ensured that NAMs are fit for regulatory use to serve the goal of ensuring health and environmental protection. The roadmap will contribute to reducing the huge backlog in hazard assessment of chemicals by applying NAMs, including read-across and grouping. This would significantly speed up processes to reduce exposure of humans and the environment to harmful chemicals.

[7] https://merlon.dtu.dk/
[8] https://www.eu-parc.eu/
[9] https://eeb.org/library/open-letter-need-to-update-reach-information-requirements/