Recommendations from a multi-stakeholder Roundtable to shape the discussion on the EU Roadmap towards phasing out animal testing for chemical safety assessments

The commitment to develop a Roadmap towards phasing out the use of animals for chemical safety assessments was part of the European Commission's response to the successful European Citizens' Initiative "Save cruelty-free cosmetics – Commit to a Europe without animal testing" launched in 2021[1]. This Roadmap aims to outline milestones and specific actions to be implemented in the short to longer term towards ultimately phasing out animal testing for chemical safety assessments.

To help advance the development of the Roadmap and define its structure, an in-person multi-stakeholder Roundtable was organised by five non-governmental animal protection organisations (Cruelty Free Europe, Eurogroup for Animals, the European Coalition to End Animal Experiments, Humane Society International/Europe, and People for the Ethical Treatment of Animals) in June 2024.

The Roundtable was attended by 41 participants representing Commission services, EU agencies, EU Member States, academia, industry, non-profit research organisations, and non-governmental organisations. The event focused on exploring and defining key elements and areas for structuring the Roadmap, and identifying pathways to facilitate the transition to a non-animal testing regulatory framework.

This initial report summarises key recommendations arising from the Roundtable discussions (see Tables 1 and 2)[2]. These recommendations are intended to support the Commission's second workshop on 25 October 2024 to discuss certain roadmap elements related to developing, validating, and implementing non-animal methods and their uptake across chemical legislation. The recommendations are not listed in order of priority and are likely to be addressed concurrently.

A more comprehensive publication detailing the Roundtable's main findings, discussion points, and recommendations will be published in the future. This publication could facilitate the ongoing work of the Commission in developing the Roadmap and guide further discussions with the wider stakeholder community. It could also serve as a reference for the development of similar Roadmaps or policy frameworks aimed at phasing out animal testing in chemical safety assessments across the globe.

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[1] European Commission. Communication from the Commission on the European Citizens' Initiative (ECI) 'Save cruelty-free cosmetics – Commit to a Europe without animal testing'. 2023. Communication available at: https://t.ly/ad9Tl

[2] It is to be noted that not all of these recommendations necessarily represent the opinion of all Roundtable participants or of the institutions represented by them.

Table 1. Key recommendations for the development and/or implementation of the Roadmap as identified during the Roundtable.

Key elements discussed during the Roundtable	Key recommendations for the development and/or implementation of the Roadmap
Coordination *To drive change and orchestrate the complex transition to a non-animal regulatory system*	• Establish a supervisory steering committee, independent from the European Commission, to oversee and guide the development of the Roadmap with defined indicators, tools and checkpoints. • Implement a robust change management framework, which should act as an overarching component providing guidance and coordination to other workstreams. • Designate a dedicated project manager or management team to oversee and streamline cross-workstream and cross-sector efforts, supported by robust reporting mechanisms. • Establish expert pools or readily available contact lists to provide timely support to the Commission on specific issues.

Analysis of the status quo
 	
To identify and document opportunities, gaps, barriers, and challenges across sectors
	• Conduct a mapping exercise, complemented with systematic reviews where appropriate, to provide a comprehensive overview of the current landscape, including:
	
	  - A clear understanding of current standards and levels of protection for human health and the environment;
	
	  - Insights into current information requirements and use of data from animal and non-animal methods for chemical safety assessments;
	
	  - An analysis of research, development, and regulatory needs;
	
	  - An analysis of opportunities to use existing and upcoming non-animal approaches;
	
	  - The determination of non-animal based Next-Generation Risk Assessment frameworks and workflows to replace current animal tests for complex endpoints;
	
	  - The identification of best practices and successful strategies from EU Member States and other (non-EU) countries.

Revision of legislation and guidance *To keep pace with advances in non-animal approaches and incentivise their use*	• On the basis of the analysis of the status quo, identify necessary changes to the legislation and adapt regulatory frameworks, chemicals legislation and guidance documents accordingly. • Simplify and harmonise the regulation of chemicals across regulatory sectors, including the removal of conflicting legislation and the use of clear, user-friendly language. • Strengthen the 'one substance one assessment' approach to foster stringent data requirements across different regulations and minimise conflicting guidance. • Pending revision of the legislation, maximise the use of existing non-animal approaches and minimise the use of animals within the current regulatory framework.

Table 1. Continued.

Key elements discussed during the Roundtable	Key recommendations for the development and/or implementation of the Roadmap
Collaboration and communication *To build an interconnected community and unified approach among all stakeholders towards phasing out animal testing for chemical safety assessments*	• Develop a comprehensive and open multi-stakeholder communication strategy. • Foster strong collaboration and build robust networks. • Ensure regular interaction between workstreams (e.g. cross-workstream meetings). • Encourage the sharing of knowledge, ideas, and technologies between different fields to strengthen cooperation and adaptability (cross-fertilisation). • Ensure open communication about existing data and processes, the limitations of the current system, and the potential of non-animal approaches. • Establish a common language that defines specific terms (such as 'safety', 'relevance', 'validation' and 'acceptance') to enable mutual understanding and effective collaboration. • Organise "transition science" masterclasses between all stakeholders to co-create solutions.
Regulatory acceptance *To facilitate and accelerate international regulatory acceptance of test methods*	• Explore (and implement, where already applicable) alternative pathways to regulatory acceptance without necessarily going through the traditional validation process, while ensuring relevance and reliability. • Establish pre-validation/qualification criteria and implementation plans for research projects with regulatory applications to streamline the process and ensure alignment with regulatory expectations. • Establish a common database for data submission across regulatory sectors and regulatory fora to enhance dialogue between stakeholders. • Expand the concept of 'safe harbours' outside of time-sensitive regulatory processes to positively influence the regulatory acceptance and use of non-animal approaches.
Global acceptance and harmonisation *To ensure the successful implementation of the Roadmap and maximise impact*	• Align the Roadmap with global initiatives and existing international frameworks that prioritise the use of non-animal approaches. • Strengthen international coordination efforts to achieve mutual acceptance of data. • Establish or appoint a dedicated cross-sectorial EU body, e.g. EURL ECVAM, to collect and evaluate existing non-animal approaches in coordination with the OECD.

Table 1. Continued.

Key elements discussed during the Roundtable	Key recommendations for the development and/or implementation of the Roadmap
Education and training *To reduce knowledge barriers, build confidence in the use of non-animal approaches and ensure their widespread adoption*	• Assess the specific education and training needs of all relevant stakeholders, e.g. regulators, industry, research institutes, and academia to ensure a targeted and impactful approach. • Identify measures to prioritise non-animal approaches in undergraduate and postgraduate programmes to equip future researchers with the necessary tools and knowledge to effectively use and interpret data from non-animal approaches.
Transparency and accessibility to knowledge and data *To promote an open science culture and increase the sharing of knowledge, data, tools, and best practices in open collaboration with all stakeholders*	• Establish a more transparent regulatory decision-making process, with particular emphasis on demonstrating that animal testing is truly used as a last resort, and provide public access to regulatory decisions. • Increase transparency in reporting the number of animals used for chemical safety assessments (including detailed breakdowns by country and sector, and the number of animals used outside the EU to comply with EU legislation). • Develop effective incentives to encourage companies to share data, and facilitate efficient data sharing of both positive and negative study results, mindful of confidential business information and competition limitations. • Create a centralised, user-friendly EU database for the compilation of non-animal testing approaches and develop a curated data repository specifically designed for artificial intelligence applications. • Encourage scientists to share their non-animal innovations with EU agencies from an early stage to accelerate both familiarity and uptake of these techniques.

Funding
 	
To ensure a sound financial base to transition to a new non-animal regulatory system
	• Estimate the costs of change and secure stable and sufficient funding, in particular to:
	
	  - Modernise and accelerate the development, validation and implementation of non-animal approaches across different sectors;
	
	  - Provide the necessary education and training;
	
	  - Build new or expand existing EU infrastructures to focus specifically on non-animal testing and the implementation of non-animal approaches into the risk assessment process;
	
	  - Better support (currently underfunded) 3Rs Centres and NETVAL laboratories;
	
	  - Establish a data-sharing system and devise a platform to foster communication and collaboration among stakeholders.

Table 1. Continued.

Key elements discussed during the Roundtable	Key recommendations for the development and/or implementation of the Roadmap
Progress metrics *To provide invaluable insights into the progress and impact of actions and allocate efforts and resources strategically*	• Establish a robust and transparent monitoring and evaluation framework, with clearly defined tools and indicators, and a functional reporting system. • Define regular checkpoints and time-bound deliverables, specific targets, and milestones for each sector stakeholder group to measure success and foster a culture of accountability. • Develop a certification or standard to incentivise and publicly recognise leaders in the field, as well as early adopters and contributors.

Table 2. Recommendations divided into five key areas to facilitate the transition to a non-animal testing regulatory framework.

Key areas discussed during the Roundtable	Key recommendations to facilitate the transition to a non-animal testing regulatory framework
Scientific development	• Define acceptable levels of uncertainty and improve understanding of current levels of protection across different regulations. • Analyse gaps and opportunities in the development and use of non-animal approaches and Next-Generation Risk Assessment. • Define and validate non-animal test strategies. • Address the scaling up of solutions, including the need for capacity building and education and training, the assessment of testing capacities of Contract Research Organisations, and the creation of a centralised non-animal data set under the EU Common Data Platform. • Develop a well-defined vision and approach, similar to a robust business case, that sets out strategic priorities with defined timelines and demonstrates clear benefits.
Regulatory implementation	• Establish well-defined criteria for regulatory acceptance and metrics for regulatory uptake. • Create 'safe spaces' for the free exchange of ideas, methodologies and data. • Develop broadly applicable weight-of-evidence systems to balance flexibility with legal certainty.

Table 2. Continued.

Key areas discussed during the Roundtable	Key recommendations to facilitate the transition to a non-animal testing regulatory framework
Validation process	• Develop a strategy to shift away from the current validation process that is seen as slow, costly and has failed to keep pace with rapid scientific progress, including the establishment of a clear and flexible framework, adaptable to different needs, depending on the sector and the context of use of the non-animal approach, and an analysis of existing systems to identify strengths, weaknesses, opportunities, and risks. • Expand, support, and fund the expert networks dedicated to coordinating and/or conducting validation studies. • Ensure close collaboration with regulatory authorities to increase the confidence of regulators in the use of non-animal approaches and accept regulatory actions based on non-animal approaches. • Define clear delineation of stakeholder roles, including a possible redefinition of the role and tasks of EURL ECVAM in the validation and acceptance of non-animal approaches. • Increase support for the development of robust case studies to effectively demonstrate practical applications and build confidence in the use of non-animal approaches.
Policy development	• Define clear protection goals for each sector, including an analysis of how well the existing protection goals are currently being met, and of areas where current protection is lacking or inadequate, such as for endocrine disruptors. • Ensure stakeholder engagement to ensure that all perspectives are considered, to promote alignment and to facilitate the development of solutions that address all relevant needs and overcome existing barriers. • Develop a large common EU cross-regulator data platform to facilitate data sharing and the setting of protection goals.
Change management	• Establish a governance framework to ensure a common approach. • Ensure cross-sectoral harmonisation. • Identify synergies to co-create. • Set clear milestones and identify clear transition indicators to track progress. • Develop a comprehensive 'change toolbox' that includes elements such as communication strategies, training programmes, information exchange platforms, and relevant case studies.

Concluding words

The multi-stakeholder Roundtable provided critical insights and actionable recommendations for shaping the EU Commission's Roadmap towards phasing out animal testing in chemical safety assessments. It aimed to help define a structure for the Roadmap by identifying key elements, workstreams, and pathways to accelerate the transition to a non-animal testing regulatory framework (to be described in a follow-up publication). The discussions underscored the complexity of transitioning to a non-animal testing regulatory framework and highlighted the necessity for a multi-faceted approach that integrates scientific, regulatory, policy, ethical, and practical considerations to structure the Roadmap effectively. Importantly, it was recognised that the Roadmap, while providing a clear path forward, should be able to accommodate a flexible network of diverse approaches, adaptable to evolving needs and scientific progress.

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[3]Disclaimer: Listing as a participant does not imply endorsement of the recommendations or represent the views of the institutions with which the participants are affiliated