Conference Report

Brussels 25 October 2024

2nd Commission Conference on the Roadmap towards Phasing out Animal Testing for Chemical Safety Assessments

EUROPEAN COMMISSION

Directorate-General for the Environment

Directorate B — Circular Economy

Unit B2 — Safe & Sustainable Chemicals

Contact: Katrin Schutte

E-mail: ENV-NON-ANIMAL-ROADMAP@ec.europa.eu

European Commission

B-1049 Brussels

Conference Report

Brussels 25 October 2024

2nd Commission Conference
on the Roadmap towards
Phasing out Animal Testing for
Chemical Safety Assessments

LEGAL NOTICE

This document has been prepared for the European Commission however, it reflects the views only of the authors, and the European Commission is not liable for any consequence stemming from the reuse of this publication. More information on the European Union is available on the Internet (http://www.europa.eu).

PDF ISBN 978-92-68-23184-5 doi 10.2779/5469181 KH-01-24-059-EN-N

Manuscript completed in December 2024

First edition

Luxembourg: Publications Office of the European Union, 2024

Contents

Executive Summary

The **2nd Commission Conference on the Roadmap towards Phasing out Animal Testing for Chemical Safety Assessments**, held on 25 October 2024, brought together key stakeholders from regulatory bodies, industry, research organisations, and NGOs to discuss the future of chemical safety assessments done using non-animal methods (NAMs) in the EU. This second conference aimed to collect input from various stakeholders on how they address the transition from animal-based testing to innovative, reliable non-animal alternatives and to report progress with the development of the roadmap, which will set out actions and milestones to drive this transformation across chemical safety assessments.

The roadmap actions will be divided into short-, medium-, and long-term actions, ensuring a structured, step-by-step approach. Participants stressed the need for a dynamic, flexible framework that adapts to scientific advances, regulatory needs, and sector-specific challenges.

A key theme was the importance of collaboration between industry, regulators, and other stakeholders. The conference underscored the need for cross-sector platforms and open dialogue, as well as iterative feedback mechanisms to support NAM adoption. Regulatory flexibility was highlighted as critical, with stakeholders advocating for more adaptable frameworks to facilitate NAM integration.

Several short-term solutions were highlighted as options for replacing, removing, or reducing animal testing within existing legal frameworks. These include replacing acute oral toxicity tests with QSAR models and substituting in vivo toxicokinetics with a combination of in vitro and in silico approaches for industrial chemicals. Efforts are also underway to propose phasing out dog studies in pesticide testing, and the ending of 90-day studies for GMOs and enzymes is being considered. For medium-term objectives, the focus will be on advancing the development, validation and acceptance of NAMs for complex endpoints, particularly systemic toxicity. Long-term goals

will aim for the complete replacement of animal testing across all regulatory endpoints, with an emphasis on establishing a new assessment framework based on NAMs.

Small and medium-sized enterprises (SMEs) were identified as facing unique challenges in adopting NAMs due to resource constraints and lack of expertise. Stakeholders recommended targeted support for SMEs, including training, financial aid, and better access to collaborative data-sharing platforms.

The importance of centralised, transparent data-sharing mechanisms was discussed as a way to support the widespread adoption of NAMs. Participants suggested creating platforms for open access to validated NAM data, regulatory acceptance criteria, and best practices.

Achieving global alignment on NAMs was also discussed. Stakeholders recognised the need for international cooperation, particularly through organisations like the OECD, to ensure the mutual acceptance of data generated using NAMs and to avoid duplication of (animal) testing.

The EU has invested significantly in NAM-related research, with over €1 billion allocated to more than 300 projects focused on alternative testing methods in the past 20 years. The EU is committed to continuing its leadership in animal welfare and the declared Union goal of phasing out animal testing, with the roadmap providing a structured approach to realising this vision.

The roadmap is set to be finalised by early 2026. Stakeholders were encouraged to continue engaging with the process, with further consultation opportunities planned for 2025. The roadmap will provide clarity and structure for the transition to non-animal testing, positioning the EU at the forefront of global efforts to promote innovative, animal-free safety assessments.

Abbreviations

3Rs	Replacement, Reduction and Refinement
3Rs	WPWorking Party on the 3Rs
ACR	Acute-to-Chronic Ratio
AFSA	Animal-Free Safety Assessment
AI	Artificial Intelligence
AOP	Adverse Outcome Pathway
APCRA	Accelerating the Pace of Chemical Risk Assessment
ASPA	ASPIS-initiated alternative Safety Profiling Approach
ASPIS	Animal-free Safety assessment of chemicals: Project cluster for Implementation of novel Strategies
BfR	Bundesinstitut für Risikobewertung
C&L	Classification and Labelling
CLP	Classification, Labelling and Packaging
DA	Defined Approach
EBW	Exposure-Based Waiving
EC	European Commission
ECHA	European Chemicals Agency
ECI	European Citizens' Initiative
ecoNAM	ecological Network for Alternative Methods
ecoTTC	Ecological Threshold of Toxicological Concern
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPAA	European Partnership for Alternative Approaches to Animal Testing
ESA	Environmental Safety Assessment
ESEC	European Specialised Expert Community
EU	European Union
FET	Fish Embryo Test
GD	Guidance Document
GHS	Globally Harmonised System
GLP	Good Laboratory Practice
HSI	Humane Society International
IATA	Integrated Approaches to Testing and Assessment
ICCS	International Collaboration for Cosmetic Safety
ICCVAM	Interagency Coordinating Committee on the Validation of Alternative Methods
ICH	International Council on Harmonisation
IMI	Innovative Medicines Initiative
IVIVE	In vitro-In vivo Extrapolation
JRC	Joint Research Centre
KE	Key Event
MAD	Mutual Acceptance of Data
ML	Machine Learning
MoA	Mode of Action
NAM	Non-Animal Method
NGO	Non-Governmental Organisation
NGRA	Next-Generation Risk Assessment
NIVA	Norwegian Institute for Water Research
NoG	Notes of Guidance
OECD	Organisation for Economic Cooperation and Development
OoC	Organ-on-Chip
OSOA	One Substance, One Assessment
PARC	Partnership for the Assessment of Risks from Chemicals
PBK	Physiologically-Based Kinetic
PEC	Predicted Environmental Concentration
PoD	Point of Departure
PNEC	Predicted No Effect Concentration
qAOP	quantitative AOP
QIVIVE	Quantitative In Vitro In Vivo Extrapolation
QSAR	Quantitative Structure-Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCS	Scientific Committee on Consumer Safety
SIR	Standard Information Requirement
SSbD	Safe and Sustainable by Design
SSD	Species Sensitivity Distribution
TG	Test Guideline
TK	Toxicokinetics
TTC	Threshold of Toxicological Concern
UN	United Nations
US	United States
WHO	World Health Organisation
WoE	Weight-of-Evidence

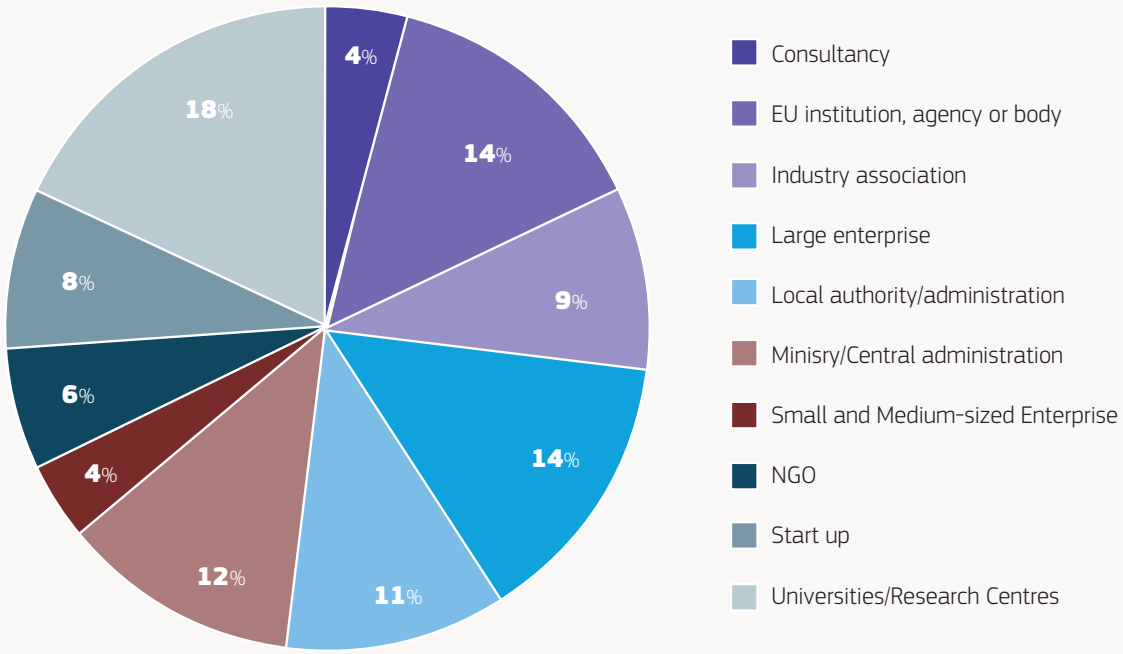
Introduction

The **2nd Commission Conference on the Roadmap towards Phasing out Animal Testing for Chemical Safety Assessments** took place as a follow-up to the initial workshop held in December 2023. The roadmap was announced by the Commission in response to the European Citizens' Initiative (ECI) "Save cruelty-free cosmetics – Commit to a Europe without animal testing", COM(2023)5041 dated 25 July 2023.

The European Commission has committed to developing a comprehensive roadmap aimed at ultimately eliminating animal testing in chemical safety assessments. This roadmap will encompass actions and milestones necessary for transitioning towards animal-free chemical legislation. The second workshop served as a platform for Member States, stakeholders, and various experts to engage in in-depth discussions on critical elements of this roadmap.

The conference provided an invaluable opportunity for stakeholders to contribute to the development, validation, and implementation of non-animal methods (NAMs). Discussions focused on options for use of these methods under different legislations, addressing regulatory acceptance, and fostering collaboration across different sectors. With the involvement of the Commission Interservice Steering Group and three specific working groups, the conference aimed to ensure that all voices were heard, and that the roadmap reflects a collective commitment to a future where chemical safety assessments no longer rely on animal testing.

Breakdown of conference participants



Session 1: State of Play of Roadmap Development

Participants

Paul Speight (DG ENV)

Katrin Schutte (DG ENV)

Georg Streck (DG GROW)

Elisabet Berggren (DG JRC)

Key Points

- Progress towards phasing out animal testing for chemical safety assessments is supported by European citizens, the European Parliament, and industry stakeholders.
- The organisation structure for the roadmap development involves an inter-service steering group and three working groups: Human Health, Environmental Safety Assessment, and Change Management.
- Short-term solutions that could be accepted for regulatory purposes in the near future are being identified to replace animal testing with non-animal methods (NAMs).
- Stakeholder input is crucial to the roadmap's development.
- Challenges include integrating new non-animal methods into existing regulatory frameworks and ensuring high standards of human health and environmental protection.
- Collaboration with international bodies and a global dialogue are essential for the roadmap's success.
- Education and training for stakeholders on the use of NAMs are necessary for effective implementation.

The conference began with an introduction that highlighted the EU's commitment to phasing out animal testing in chemical safety assessments. This commitment aligns with EU legislation aimed at animal welfare, responding to public and industry demands for cruelty-free approaches. The opening remarks recognised the efforts made by European citizens, with over a million signatures collected to strengthen the EU's ban on animal testing for cosmetics and extend this approach to broader chemicals legislation. This European Citizens' Initiative demonstrates significant public support for a transition to non-animal methods, which the Commission aims to address through the roadmap.

The roadmap is a considerable project that will guide the EU's transition toward non-animal testing methods in multiple sectors, including, among others, industrial chemicals, pesticides, biocides, food additives, and pharmaceuticals. Historically, the EU has relied on animal testing to inform safety and regulatory classifications under frameworks like the EU Regulation on Classification, Labelling, and Packaging (CLP) of chemical substances, and globally through the UN's Globally Harmonised System. However, with emerging non-animal technologies, there is growing momentum to shift the regulatory paradigm to ensure safety without relying on animals. The Commission aims to release the final roadmap by early 2026, following robust consultation with stakeholders from civil society, industry, regulatory agencies, and research communities.

Progress and structure of working groups

European Commission representatives at the conference provided an update on the organisational structure and progress of the roadmap. Led by the Directorate-General for Environment (DG ENV) and the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), this roadmap development effort is supported by an inter-service group comprising other Commission services and EU agencies, including ECHA, EFSA, and EMA. To address specific areas of animal testing replacement, three dedicated working groups have been established: Human Health, Environmental Safety Assessment, and Change Management. These working groups will inform the actions and milestones outlined in the roadmap, providing sector-specific insights and recommendations.

Since the previous conference in December 2023, the inter-service group has convened several times to define the roadmap's structure, terminology, and legislative scope. The roadmap encompasses fifteen areas of legislation covering chemicals, pesticides, biocides, pharmaceuticals, and workplace safety, among others. Each working group has met multiple times to identify short-term and long-term solutions for reducing reliance on animal testing.

The **Human Health Working Group** has started with identifying existing animal testing requirements across EU chemicals legislation and exploring viable alternatives. Recognising that some testing requirements are outdated, the group has proposed several replacement strategies that are either ready for immediate implementation or require further testing under existing frameworks. Examples include replacing in vivo toxicokinetics with a combination of in vitro and in silico models for industrial chemicals and considering the elimination of certain tests currently required for pesticides and genetically modified organisms (GMOs), that may no longer be necessary.

The working group is considering a case study on acute systemic toxicity as a model to illustrate step by step how to achieve regulatory acceptance of alternative approaches across sectors. Additionally, the group is compiling further short-term replacement possibilities and examining ways to address complex endpoints, where new approaches are still missing. For these complex endpoints, research into suitable approaches is still required and the group will aim to give guidance as to what information the new models should deliver. To further this effort, the Human Health Working Group collaborates closely with other projects and agencies, such as the PARC and ASPIS projects and ECHA, EFSA and EMA to develop a unified framework that regulators can rely on when evaluating new approaches.

For long-term change, the group has discussed the need for criteria that define regulatory acceptance and the

"IT IS ONLY WHEN WE ARE ALL UNITED IN OUR EFFORTS TOWARDS PHASING OUT ANIMAL TESTING, STAKEHOLDERS, REGULATORS AND CIVIL SOCIETY, THAT THIS ROADMAP CAN BE A SUCCESS."

performance of new methods across various sectors. These criteria are intended to guide stakeholders in designing non-animal testing methods that meet regulatory requirements while accommodating sector-specific differences.

The **Environmental Safety Assessment Working Group** focuses on identifying animal testing requirements within environmental safety assessments and exploring alternative solutions. This group which, like the Human Health working group, comprises representatives from the Commission, key EU agencies, and industry stakeholders, is currently prioritising short-term replacement options. One specific focus has been on testing requirements for vertebrates, with discussions on whether these requirements could be adapted to accept data from non-vertebrate or entirely animal-free methods where possible. The working group's initial objective is to phase out animal testing for environmental safety assessments gradually, beginning with vertebrate species.

The roadmap for environmental safety will address several aspects: determining regulatory actions, integrating scientific advancements, and consulting with stakeholders. Specific actions considered within this group include the proposal of methods to replace fish acute toxicity testing, an area with promising alternatives. The European Partnership for Alternative Approaches to Animal Testing (EPAA) has also contributed by providing scientific insights and short-term replacement options, particularly for areas where regulatory frameworks may need adjustment to accept new approaches.

The **Change Management Working Group** is tasked with considering actions that support the transition process to animal-free chemical safety assessments; it addresses barriers and facilitates cross-sectoral collaboration to implement the roadmap effectively. The working group aims to create a foundation for long-term success by setting milestones, establishing trust among stakeholders, and promoting a shared understanding of the roadmap's goals. The group has not invited external stakeholders to its first meetings, at which initial discussions have established its key priorities. Meanwhile a series of bilateral meetings with different stakeholders is taking place, aiming to receive input from stakeholders on all aspects of change management.

One priority is to foster transitional initiatives: these are projects or actions that bridge the current reliance on animal testing with a future of non-animal methods. These initiatives will include specific outputs, such as new testing protocols, and outcomes that contribute to regulatory acceptance and use. The working group encourages stakeholders to submit proposals for transitional initiatives[1] that directly support the roadmap's objectives.

Another critical focus is the development of indicators to track progress, particularly by measuring the reduction of animal testing and the integration of NAMs in regulatory settings. Indicators may include the number of non-animal methods introduced into EU legislation and the relative use of animal versus non-animal tests across various chemicals. Additionally, the group is engaging various stakeholders in bilateral discussions to understand sector-specific concerns and approaches to change management, which will help shape collaboration models.

The Change Management Working Group also emphasises the importance of creating a safe space where stakeholders, particularly regulators and industry representatives, can collaborate openly without fear of scrutiny. This approach allows for candid discussions and brainstorming, facilitating trust and the co-creation of solutions.

The **Session 1 Q&A session** underscored the importance of stakeholder engagement and clarified several issues related to the roadmap's development. One participant highlighted the PREMIER project, which focuses on environmental risk assessment in the pharmaceutical sector. This project aims to prioritise NAMs for pharmaceutical assessments, potentially reducing animal testing. The Commission acknowledged this initiative and reiterated its commitment to considering all relevant projects in the roadmap's development.

Questions were raised about working group compositions and whether academia, as a primary developer of NAMs, should have a stronger presence. In response, the Commission explained that while working groups need to remain manageable, feedback from academic sources is integrated e.g. through representation from partnerships like PARC and ASPIS.

Other participants inquired about the proposed advisory scientific committees and whether they would ensure objective evidence assessment. While the roadmap may lead to the establishment of such committees, the decision is still under review, with further stakeholder consultation required to determine if current structures are adequate or if new committees are needed.

The discussion also addressed legislative changes needed to support NAM adoption. For short-term solutions, minor adjustments may suffice; however, long-term goals for systemic toxicity and chronic endpoints require a more extensive regulatory transformation. The roadmap will likely outline a preliminary framework, with further refinement required after 2026 to fully accommodate NAMs in chemical safety assessments. Modification of EU legislation follows the normal procedures for such changes in the respective legislative area.

Another key question concerned existing animal data and how it will be incorporated alongside NAMs in future assessments. The Commission indicated that while existing data can serve as a reference, the goal is to develop more human-relevant, and ethical testing strategies that may eventually supersede the need for animal data altogether.

The session concluded with calls for training programmes to help stakeholders adapt to new testing methods. The Commission expressed its commitment to working with contract research organisations (CROs) and training providers to support companies, especially SMEs, in adopting NAMs. Furthermore, participants suggested that the Scientific Committee on Consumer Safety (SCCS) be included more visibly in roadmap initiatives, as its expertise with non-animal methods can provide valuable insights.

1 Transitional initiatives - European Commission

Session 2: Contributions to Roadmap from Stakeholders

Participants

Matthias Herzler (BfR)
Julia Pochat (Eurogroup for Animals)
Gavin Maxwell (Unilever)
Sylvia Escher (Fraunhofer)
Ferran Sanz (Pompeu Fabra University)
Thomas Steger-Hartmann (Bayer)

Key Points

- NGRAroute, PARC's proposal for a roadmap for next-generation risk assessment, now supports the Commission roadmap.
- Centralised platforms and knowledge-sharing systems, such as PARCopedia, enable stakeholders to align on progress and minimise project redundancies.
- EPAA activities are bridging research to regulatory use, building confidence in non-animal methods, and transitioning to a new global regulatory paradigm.
- ASPIS's ASPA framework integrates various NAMs for systemic toxicity assessments and aims to expand to other endpoints.
- VICT3R focuses on creating virtual control groups to reduce animal use in toxicology research, with an emphasis on regulatory acceptance.
- Effective roadmap implementation requires harmonisation across global regulatory standards and collaboration across industries.

The first presentation provided an overview of the European **Partnership for the Assessment of Risks from Chemicals** (PARC) and its project on developing a roadmap for next-generation risk assessment (NGRAroute). The vision outlined by a representative from the German Federal Institute for Risk Assessment highlighted a fully animal-free NGRA, aiming to address both human health and environmental considerations.

The PARC partnership involves nine work packages, of which four focus on generating data, methods, and tools, while the others coordinate overarching activities. A core product of Work Package 2 is the roadmap for NGRA implementation and a collaborative platform, PARCopedia, which facilitates the dissemination and exchange of knowledge. The NGRA model seeks to replace animal testing for chemical safety assessments through integrated approaches that combine various NAMs. This framework includes in vitro, in silico, and mechanistic models designed to meet regulatory requirements.

"THE VISION IS TO HAVE AN ANIMAL-FREE NGRA IMPLEMENTED AS THE DEFAULT APPROACH TO CHEMICAL RISK ASSESSMENT IN EU CHEMICALS LEGISLATION EVENTUALLY."

The transition toward NAMs is viewed as a phased process, starting with simpler endpoints that are currently manageable without animal tests, such as skin sensitisation. However, more complex endpoints, such as systemic toxicity, require more comprehensive frameworks where NAMs are applied collectively to provide necessary regulatory outputs. PARC's NGRA framework advocates for a modular design, allowing it to be adapted to specific regulatory needs or problem formulations.

The presenter also highlighted 10 guiding principles for NGRA, focusing on providing an adequate protection level for human health and the environment, integrating diverse data types, and ensuring scalability across toxicity pathways. These principles reflect a commitment to scientific reliability and regulatory acceptance, with emphasis on harmonisation across regulatory contexts to meet both EU and international standards.

NGO contributions – recommendations from June 2024 roundtable

A representative from Eurogroup for Animals presented insights from a roundtable held in June 2024, which convened NGOs, industry representatives, regulatory bodies, and scientific researchers. This roundtable aimed to support the development and implementation of the EU roadmap by identifying priorities and challenges.

Several key elements emerged from the discussions, including the need for strong coordination, transparency, and centralised knowledge-sharing mechanisms to avoid duplication of efforts. NGOs advocated for a supervisory committee to oversee the transition to non-animal methods, calling for a structured approach to addressing existing regulatory and technical gaps. Roundtable participants identified critical areas for collaboration and communication to foster robust stakeholder networks that can facilitate co-creation and alignment across sectors.

NGOs also highlighted the importance of regulatory acceptance, suggesting improvements to validation systems that would streamline international acceptance of NAMs. Global harmonisation was underscored as essential, given the widespread impact of regulatory changes across industries, especially those operating internationally. Additionally, education and training initiatives were proposed to ensure that all stakeholders, from regulators to research organisations, are informed and equipped to transition effectively to NAMs.

Update on EPAA activities

The **European Partnership for Alternative Approaches to Animal Testing** (EPAA) provided an update on its initiatives to bridge the gap between research on NAMs and their regulatory application. Founded in 2005, EPAA is a partnership involving the European Commission and eight industry sectors, including pharmaceuticals, chemicals, pesticides, cosmetics, and household care.

EPAA's activities focus on three primary goals: bridging research and regulatory use, building confidence in NAMs, and supporting a transition to a global regulatory paradigm. To achieve these, EPAA hosts discussions and fora that gather industry, regulatory, and scientific stakeholders to review NAM frameworks and identify gaps that require additional research.

Among EPAA's ongoing projects is a cross-sector review of NAM-based frameworks for endocrine disruption, which seeks to capture insights and encourage cross-industry dialogue. Another success has been the NAM Designathon Challenge, which looks at developing a future classification system for systemic toxicity based on NAMs only. Another initiative involves developing a virtual waiver for carcinogenicity testing, enabling the replacement of long-term animal studies in agrochemical assessment with NAMs. EPAA is also exploring the potential of case studies to demonstrate the practical utility of NAMs in addressing regulatory requirements for acute and systemic toxicity.

EPAA underscored the value of building confidence in NAMs through case studies and regulatory engagement. Such initiatives enable stakeholders to evaluate NAMs in real-world scenarios, ultimately fostering trust and acceptance of these methods. To advance this effort, EPAA is planning a workshop on NAMs in March 2025, aimed at discussing the status of the science around next-gen or animal-free chemical safety assessment and fostering alignment with the Commission's roadmap.

ASPIS cluster and the ASPA framework

A representative from the ASPIS cluster presented updates on the **ASPIS-initiated Safety Profiling Algorithm** (ASPA), a tiered NGRA framework under development by three ASPIS projects: ONTOX, PrecisionTOX, and Risk-Hunt3r. ASPA integrates diverse NAMs to provide a mechanism-based, human-centred framework for systemic toxicity assessment, designed to meet various regulatory requirements.

ASPA's structure comprises multiple building blocks, including hazard, pharmacokinetics, and exposure modules. The hazard component, for example, begins with high-throughput methods and progresses to more complex mechanistic analyses if initial data is inconclusive. The framework is adaptable, enabling it to incorporate new NAMs as they become validated and allowing cross-application across multiple toxicity endpoints.

Two case studies illustrate ASPA's capabilities. One addresses the role of metabolism in assessing chemical toxicity, while another explores the potential for high-throughput methods to predict toxicity classifications. These case studies offer practical examples how ASPA could be incorporated into regulatory workflows. ASPA's implementation is supported by an interactive dashboard tool, "Namastox," developed to guide users through the decision framework, ensuring consistent application of the ASPA methodology.

The ASPA framework has been shared publicly, and the project team welcomes feedback from stakeholders to enhance its usability and ensure it aligns with regulatory expectations. The ASPIS cluster anticipates further collaborations with PARC to harmonise NGRA frameworks and improve the consistency of NAMs used across sectors.

VICT3R – virtual control groups for toxicology

The final Session 2 presentation discussed the **VICT3R project**, which is coordinated by academia (Pompeu Fabra University) and the pharma industry (Bayer). This initiative focuses on developing virtual control groups to reduce the need for live control animals in repeated-dose toxicity studies. By collecting historical control group data across various studies, VICT3R aims to create simulated control groups that can replace physical control groups, reducing animal use by up to 25%.

The project builds on legacy data gathered in earlier IMI initiatives and applies artificial intelligence to generate statistically robust control datasets. With 33 partner

organisations and an international advisory group, VICT3R emphasises regulatory acceptance as key to the project's success. Preliminary results suggest that virtual control groups can yield comparable results to conventional controls, supporting their use in regulatory toxicology.

One goal is to establish ongoing dialogue with regulatory authorities, such as the EMA and OECD, to facilitate the acceptance of virtual control groups. The project also highlights potential cost savings and improved data interpretation as additional benefits of reducing live animal controls. By contributing to the EC roadmap, VICT3R seeks to expand NAM applications in the short term while supporting a shift to fully animal-free regulatory assessments in the long term.

The session closed with a **Q&A discussion** focusing on the alignment of multiple initiatives within the NAM landscape. Participants raised concerns about potential project redundancies, prompting clarification that overlapping activities are often complementary and intended to address specific regulatory contexts. The roadmap and platforms like PARCopedia were noted as essential tools for coordinating research and regulatory acceptance.

A question about the ASPA framework's current focus on human health led to a discussion on integrating environmental considerations. While ASPA currently targets human health, the presenters recognised the potential to expand it to environmental applications. Other questions explored the need for international collaboration, particularly in harmonising NAM adoption across regulatory bodies such as the FDA and OECD. Panellists acknowledged ongoing efforts to coordinate NAM initiatives globally, emphasising that a shared understanding of safety standards is critical for effective implementation.

Another attendee asked about legal challenges to NAMs, noting cases where regulatory decisions based on NAMs were contested in court. Respondents highlighted that confidence in NAMs grows through peer-reviewed case studies, which validate their reliability in specific regulatory decisions. The session concluded with an appeal for broader stakeholder engagement in NAM discussions, underscoring the importance of cross-sector alignment for the roadmap's long-term success.

Session 3: International Test Guidelines, Validation, Qualification, and Standardisation

Participants

Georg Streck (DG GROW)

Jelle Vriend (RIVM),

Maurice Whelan (DG JRC)

Katrin Schutte (DG ENV)

Mounir Bouhifd (ECHA)

Chantra Eskes (EFSA)

Orla Moriarty (EMA)

Kirsty Reid (EFPIA)

Jay Ingram (HSI)

Key Points

- Numerous EU structures support NAM validation, but alignment and collaboration among agencies, Member States, and industry are needed.
- OECD guidelines are critical for international alignment, though additional sector-specific qualifications may be necessary.
- Funding is a primary hurdle for NAM validation; greater investment and collaboration could streamline processes.
- A coordinated action plan focusing on stakeholder inclusion, global collaboration, and clarification of validation terminology is essential for long-term success.

The session began with an overview of the organisational structures in place within the EU that support the validation of NAMs. Several institutions play key roles in this landscape, including the European Union **Network of Laboratories for the Validation of Alternative Methods** (NETVAL) and the PARERE network of regulatory advisors, both overseen by the European Commission's Joint Research Centre (JRC). These networks focus on facilitating validation studies and ensuring that NAMs are scientifically robust and suitable for regulatory applications. NETVAL comprises 33 laboratories, primarily contract research organisations (CROs), with substantial expertise in quality control systems like Good Laboratory Practice (GLP).

The JRC's **EU Reference Laboratory for Alternatives to Animal Testing** (ECVAM) also supports the coordination of validation studies and offers the independent peer review of non-animal methods through the ECVAM Scientific Advisory Committee (ESAC). The JRC works actively with the OECD to bring validated methods into OECD test guidelines, which are essential at the international level for regulatory acceptance across jurisdictions.

Representatives from the European Medicines Agency (EMA) highlighted the Agency's 3Rs Working Party, which serves as a focal point for interactions with stakeholders regarding NAM validation in the pharmaceutical sector. EMA's Innovation Task Force further facilitates early engagement with method developers, offering guidance to align new approaches with regulatory needs. This structure provides an opportunity for early feedback, helping to prioritise methods that can meet regulatory requirements, which ultimately increases their chances for regulatory acceptance.

The role of OECD guidelines and harmonisation

The discussion then shifted to the importance of OECD guidelines in the validation and acceptance of NAMs. These guidelines, which serve as international standards, are pivotal for regulatory acceptance across sectors. Representatives from the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) emphasised that OECD guidelines not only ensure mutual acceptance of data but also bring robustness and trustworthiness to validated methods. For ECHA, these guidelines are consistent with Classification, Labelling, and Packaging (CLP) regulation criteria, supporting the comprehensive REACH database, which currently includes over 100,000 registration dossiers.

However, there are some challenges in fully relying on OECD guidelines across different sectors. EFSA representatives highlighted that even within the EU, data requirements vary significantly across sectors, which complicates harmonisation efforts. For instance, while the CLP regulation for chemicals requires adherence to specific guidelines, EFSA's standards for risk assessments, particularly for novel products like nanomaterials, call for alternative approaches to fill data gaps when standard methods are not applicable. These sectoral differences indicate a need for greater internal alignment within the EU.

In the pharmaceutical sector, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) operates as an additional body to the OECD, particularly in areas unique to pharmaceuticals. Although ICH ensures harmonisation across global markets, it is a slow and complex process, and the need for faster adoption of NAMs remains a challenge.

Financial and structural challenges in NAM validation

The validation process for NAMs, while essential, presents significant financial and logistical challenges. The JRC expressed concern about limited funding for these studies, based on their experience gained from coordination of NAM validation studies over the past two decades. While the JRC can contribute coordination expertise, resources for conducting full-scale validation studies are inadequate. Industrial associations and CROs are increasingly involved, but validation efforts need greater financial support and incentives, especially for emerging SMEs and start-ups developing novel methods.

There is growing interest in leveraging public-private partnerships to fund NAM validation. Industry representatives called on the European Commission to take a strategic role in coordinating such partnerships, suggesting the establishment of a central life sciences office. This office could oversee NAM validation priorities, establish partnerships, and channel funding from EU research programmes. Sustainable funding would ensure continuity and help avoid situations where validated methods are left unused due to lack of follow-up support.

The EPAA has been instrumental in this space, supporting cross-sector initiatives with limited funding. However, EPAA's resources are not sufficient to support all necessary validation activities. Member State involvement is also crucial, as national contributions could enhance existing resources and foster a stronger commitment to NAM development across Europe.

Qualifications for context-specific use

The EMA and EFSA presented on qualification processes, which are essential for aligning NAMs with specific regulatory contexts. At EMA, the established qualification process for NAMs is heavily based on the context of use - the particular and context-dependent regulatory purpose the method is designed to address. EMA encourages the submission of NAM data alongside traditional methods to gradually build confidence in non-animal approaches. This strategy allows regulators to evaluate NAMs in a controlled manner, fostering gradual acceptance of these methods in pharmaceutical assessments.

EFSA is exploring qualification of NAMs for novel areas like nanomaterials. In a recent initiative, EFSA mapped over 260 NAMs for nano-specific risk assessment, finding that while many NAMs are scientifically promising, they lack full validation. To address this, EFSA is working on a qualification proposal for NAMs in nanomaterial assessments, which includes collaboration with the FDA and other international bodies. This interagency alignment highlights the necessity of adapting qualification processes across sectors to support the broader acceptance of NAMs.

Both EMA and EFSA stressed the need for training and capacity-building initiatives to ensure regulatory authorities are well-prepared to assess NAM data. This would include tailored guidance on applying new methodologies in specific contexts, allowing regulators to evaluate NAMs more confidently and effectively.

The need for a coordinated validation system

One recurring theme in the session was the need for a unified, coordinated system for NAM validation in the EU. As the JRC and other participants pointed out, coordination of validation studies requires complex planning and resources. While some industry associations and CROs have taken on active roles, a more centralised approach is needed to avoid redundancies and ensure consistent quality standards across sectors.

The Communication replying to the European Citizens' Initiative states that, with the roadmap development, the Commission will analyse the need for advisory scientific committees, e.g. to provide guidance on validating and standardising new test methods. The Environmental Safety Assessment working group is evaluating whether existing EU structures can support this effort or if additional committees are necessary. This consultation process includes assessing whether current frameworks at the OECD and EU levels are equipped to support regulatory acceptance, or if a more targeted approach is needed for specific testing requirements.

One solution proposed was to establish a pan-European entity or framework dedicated to overseeing NAM validation, involving close collaboration with research consortia, regulatory bodies, and CROs. This framework would provide clear guidance on validation requirements and facilitate data sharing to prevent repetitive studies. Furthermore, a dedicated validation body could standardise approaches across sectors, accelerating regulatory acceptance of NAMs and enabling cross-sector applications.

"WE NEED TO INVOLVE ALL THE STAKEHOLDERS - INDUSTRY, REGULATORS, ACADEMIA, NGOS, PATIENT GROUPS - TO MAKE SURE THAT WHAT WE'RE DEVELOPING COVERS AND ADDRESSES ETHICAL CONCERNS AND ALSO MAINTAINS SCIENTIFIC CREDIBILITY."

The financial aspect of validation studies was highlighted as a major concern. Without incentives, industry stakeholders may lack motivation to invest in NAM validation. Therefore, participants suggested that EU institutions explore incentive models, possibly linking NAM adoption to regulatory benefits or financial support. Member State funding and EU-wide grants could play a pivotal role in creating sustainable validation mechanisms that align with the roadmap's long-term goals.

Roadmap action points and stakeholder recommendations

The final discussion focused on key action points for the roadmap, emphasising alignment and collaboration across stakeholders. One recommendation was for the roadmap to establish clear criteria for regulatory acceptance of NAMs, which would provide consistency and foster industry confidence. Participants advocated for terminology alignment across sectors to avoid confusion about validation, qualification, and acceptance processes.

Participants also stressed the importance of international collaboration. Global alignment is crucial for multinational companies developing products for diverse markets. By ensuring that NAMs validated in the EU are accepted internationally, the roadmap can prevent duplicative testing and promote broader acceptance of non-animal methods. In the pharmaceutical sector, this global approach would reduce barriers for NAM integration, enabling consistent testing standards across regions.

Additionally, stakeholders highlighted the need for a coordinated training programme on NAMs, targeting regulatory authorities, industry representatives, and research organisations. Such training would foster a common understanding of regulatory needs and validation processes, supporting effective implementation of NAMs. Training at multiple levels, including academic curricula and regulatory workshops, would ensure that NAM principles are widely understood and applied.

A further recommendation was to conduct a comprehensive review of health protection goals and ensure that regulatory frameworks reflect these updated standards. This approach would clarify how NAMs align with evolving health protection objectives, enhancing their relevance to current regulatory challenges. Such a review would help define a modern regulatory framework that fully accommodates NAMs, without relying on legacy animal-based methods.

Session 4: Transitional Initiatives

Participants

Andrew Worth (DG JRC)

Kerstin Kleinschmidt-Doerr (EFPIA)

John Chave (Cosmetics Europe)

Petra Kern (CEFIC)

Key Points

- Transitional initiatives act as a bridge for shifting from animal testing towards alternative methods across regulatory and industrial frameworks.
- A 'three-baskets approach' aids industries by sorting animal testing methods based on the current scientific viability of alternatives.
- A catalogue of transitional initiatives has been launched as a living, dynamic platform to foster collaboration, support ongoing innovation, and monitor roadmap implementation.
- Global collaboration and stakeholder engagement is crucial for harmonising approaches, sharing resources, and accelerating the adoption of non-animal testing solutions worldwide.
- Technology availability, regulatory acceptance, and the scalability of new methods should be emphasised to ensure wide adoption of non-animal solutions across sectors.

Session 4 opened with an introduction to the transitional initiatives concept, a pivotal step in achieving the roadmap's goal of reducing animal testing across regulatory contexts. The speaker, representing the Change Management working group, outlined the challenges inherent in such a transition, emphasising the need for change at multiple levels - individual, organisational, and regulatory. While there has been extensive discussion on the scientific and ethical aspects of moving away from animal testing, actualising this shift requires actionable solutions that accommodate the complexities of varied industries and regulatory frameworks.

Language and discourse, particularly through metaphors, play a crucial role in guiding the shift from animal testing by fostering shared understanding and direction. The 'roadmap' metaphor, for example, conveys a structured journey marked by sequential steps, milestones, and a final goal. In contrast, a 'transition pathway' metaphor emphasises the need for fluidity and adaptability, highlighting that progress is rarely straightforward and often requires continuous input and adjustments. This perspective acknowledges the reality of setbacks and advances, underscoring the importance of flexibility in navigating complex shifts. Finally, an 'interwoven threads' metaphor addresses the complexity of the transition, suggesting that solutions depend on the integration of contributions from multiple scientific, technological, and regulatory fields.

The speaker also introduced the concept of transitional initiatives as a possible action in the roadmap. Transitional initiatives were described as projects or actions that contribute to reducing or replacing animal testing. Each initiative is expected to have clear outputs and outcomes. Outputs are tangible results, such as a new testing method, whereas outcomes refer to the broader changes achieved, such as regulatory adoption. This distinction is important as it enables monitoring of both immediate contributions and longer-term impacts.

To support these initiatives, a catalogue of transitional initiatives was launched. This catalogue will serve as a dynamic, online resource for tracking projects that contribute to the roadmap. Unlike the roadmap, which is a static document, this catalogue will be continually updated, enabling it to evolve with new insights, technologies, and regulatory changes. Its key purposes include embracing complexity by allowing stakeholders to document the non-linear progress of transitional initiatives. It also aims to facilitate learning from others, enabling participants to share insights and lessons, thereby accelerating progress by building on existing knowledge and avoiding duplication of efforts. As a living document, the catalogue will also assist in planning future initiatives by identifying gaps, proposing new initiatives, and fostering collaboration across sectors.

Ultimately, the catalogue is envisioned as a resource for large language models and AI systems, enabling future use of artificial intelligence to identify trends, propose new initiatives, and monitor progress in real time. The speaker concluded by encouraging stakeholders to contribute actively to the catalogue.

The pharma industry's 'three-basket' approach

A representative from EFPIA introduced their three-basket approach, a pragmatic method for classifying animal testing practices based on the availability of alternative methods. This approach was developed as a practical framework to prioritise action and guide decision-making within organisations.

The three baskets are defined as follows:

1. **Basket One** includes all animal tests for which mature, scientifically validated alternatives already exist, or where animal testing provides minimal added value. This basket includes cases where animal testing is performed solely to meet regulatory requirements, even though alternative methods could yield equivalent data.
2. **Basket Two** contains tests for which alternatives are still in development or require further validation. Examples in this category include organoids, in silico methods, and digital twins - innovative techniques that hold promise but are not yet fully mature or widely accepted.

3. **Basket Three** consists of tests with no current viable alternatives. This includes complex testing needs where scientific or technological solutions have yet to be discovered.

The speaker emphasised that the three-basket approach provides a structured yet adaptable strategy. By organising testing activities into these baskets, organisations can more easily prioritise immediate implementation of validated alternatives (Basket One), allocate research and development funds towards promising alternatives (Basket Two), and continue necessary animal testing with a commitment to refinement (Basket Three). This approach also helps organisations avoid getting "stuck" in unproductive debates over animal testing by focusing on what can be feasibly achieved today, with a long-term goal of reducing reliance on animals.

To facilitate the global adoption of this approach, the industry is actively engaging with international stakeholders, aiming to harmonise regulatory expectations and encourage universal acceptance of validated alternatives. This effort is crucial to prevent redundancy in testing requirements across different jurisdictions and to support broader, faster adoption of alternatives.

Transition experience in the cosmetics sector

A representative from the cosmetics industry provided a historical overview of the sector's transition from animal testing to alternative methods, which culminated in a full ban on animal testing in 2013. This shift was driven by both ethical concerns and business necessities. The cosmetics sector has long been influenced by consumer opposition to animal testing, leading to early investments in non-animal methods. A significant milestone in this journey was the Standing Committee for Alternatives to Animal Testing (SCAAT), established in 1992 to coordinate industry-wide initiatives.

After the 2013 ban, the cosmetics industry sustained its efforts through a long-range science strategy that relied on collaboration with stakeholders, including regulators, animal welfare NGOs, and suppliers. This strategy led to significant achievements, such as the launch of over 70 projects aimed at developing alternative testing methods. The industry also contributed to standardisation efforts by publishing numerous OECD documents, case studies, and peer-reviewed papers that promote and validate these alternatives. Additionally, the strategy facilitated the formation of an industry consortium dedicated to advancing research on non-animal methods and providing guidance to support regulatory alignment.

To address the global nature of animal testing challenges, the cosmetics industry formed the International Collaboration for Cosmetic Safety (ICCS). This new association brings together stakeholders from various regions, including suppliers and NGOs, to foster collaboration, share resources, and collectively advance the use of alternatives. The speaker stressed that collaboration across sectors and regions is essential for addressing regulatory challenges, which vary significantly across jurisdictions.

A critical goal of the cosmetics industry is to make non-animal methods accessible to all, including SMEs. The industry recognises that large corporations often have more resources to invest in alternative methods, but for widespread adoption, SMEs must also be able to access these tools. The ICCS aims to address this disparity by providing education, resources, and support to help SMEs transition to non-animal testing methods.

Chemical sector's approach to the roadmap

The chemical industry faces unique challenges in transitioning to non-animal methods, particularly due to the need for both hazard identification and risk assessment. A representative from the sector outlined the industry's approach to the roadmap, focusing on ensuring product safety while phasing out animal testing. The industry's primary challenge lies in developing and validating alternative methods that meet regulatory requirements across a wide range of chemical classes.

The chemical sector's approach is based on collaboration and resource-sharing. Industry stakeholders work closely with international research institutes and regulatory

bodies to develop methods suitable for regulatory acceptance. One proposed solution is a science discussion platform or "safe space" where companies can present alternative methods to regulators for preliminary feedback before formal regulatory submission. This platform would allow companies to test novel methods without risking rejection, thereby increasing confidence in non-animal approaches.

Another significant challenge for the chemical industry is predictability. For businesses to invest in alternative methods, they need assurance that regulatory frameworks will support these changes. Predictable, harmonised regulations would allow companies to transition smoothly, without the risk of conflicting requirements that could delay progress.

To address these challenges, the chemical sector has engaged in joint research projects, case studies, and workshops with various stakeholders. The goal is to build a body of evidence supporting the reliability of non-animal methods, which can then be used to advocate for regulatory acceptance. The industry also recognises the importance of scalability; for alternatives to be viable, they must be applicable across the entire chemical sector, from multinational corporations to smaller companies.

The session concluded with an interactive **Q&A discussion**, where participants raised several key points about the practicalities and philosophical aspects of the transition to non-animal methods. A prominent theme was the need for standardised terminology. A consensus emerged on the importance of defining terms clearly, especially when discussing shared goals across industries.

One question explored the catalysts for mindset change in the cosmetics sector, specifically how this shift has been achieved and could be replicated in other industries. The speaker noted that in the cosmetics sector, both ethical considerations and practical business needs drove change. The ethical opposition to animal testing has always been strong among consumers, but the regulatory ban created a business imperative that further incentivised the industry to innovate. This dual motivation - ethics and necessity - has helped the cosmetics sector to invest heavily in alternatives and lead by example.

Participants also discussed how to foster a positive, proactive mindset toward transitional initiatives in other sectors. Some suggested that creating safe spaces where companies can trial non-animal methods and gain feedback could help build confidence in these approaches. The concept of a "sandbox" was proposed, where organisations could experiment with alternatives without the pressure of immediate regulatory acceptance.

Finally, participants raised questions about the proposed catalogue of transitional initiatives and the role of the three-basket approach. A clarification was sought on how to avoid overlaps between different "basket" approaches, with the industry representative stressing the importance of consistency in how baskets are defined and applied. The transitional initiatives catalogue was confirmed as a living platform open to ongoing contributions, allowing initiatives to be continually added and evaluated.

The session concluded with a call to action, encouraging participants to actively submit their initiatives to the catalogue. This resource will enable stakeholders to collaborate, monitor progress, and identify synergies, ultimately supporting the successful implementation of the roadmap.

"ONE THING THAT IS IMPORTANT FOR BUSINESS TO KEEP RUNNING IS THAT WHATEVER HAPPENS IN THESE TRANSITION STEPS, THE TRANSITION STEPS NEED TO BE PREDICTABLE."

Session 5: Stakeholder Input on Actions and Milestones for the Roadmap

Participants

Georg Streck (DG GROW)
Sonja Beken (MS, BE)
Katia Lacasse (CEFIC)
Gavin Maxwell (EPAA)
Marco Corvaro (CropLife Europe)
Caroline Bassoni (SME, Cosmed)
Emma Grange (Cruelty Free Europe)
Ninja Reineke (Chemsec)

Key Points

- It is important to set clear, actionable targets across short, medium, and long-term actions to track progress toward phasing out animal testing.
- There is a need to enhance regulatory flexibility, streamline the validation process, and establish a supportive framework for early NAM use across sectors.
- Building a collaborative platform involving Member States, NGOs, and CROs is seen as essential to the roadmap's success.
- For small and medium-sized enterprises (SMEs) there is a need for dedicated training, accessible data-sharing mechanisms, and long-term investment security to support NAM adoption.
- Establishing centralised mechanisms for transparency and data-sharing will allow for efficient regulatory and cross-sector adoption of NAMs.

Session 5 of the conference focused on gathering insights from diverse stakeholders regarding the specific actions and milestones necessary for the roadmap towards eliminating animal testing. The discussion highlighted the importance of adopting a structured, phased approach, encompassing short-, medium-, and long-term actions and milestones. This framework would allow stakeholders to break down the transition into manageable stages, ensuring that progress could be tracked and assessed. Emphasis was placed on the need for cross-sector collaboration, transparent data-sharing mechanisms, and resource allocation to support a smooth transition to phasing out animal testing.

A central theme throughout the session was the need for the roadmap to be a dynamic and actionable framework. Stakeholders emphasised that to be effective, the roadmap should go beyond generic goals to specify clear, tangible steps. The conversation underscored the significance of establishing clear and actionable milestones throughout the roadmap, with participants advocating for a phased, step-by-step approach. Such a structure would allow each stage to build on the previous one, laying the groundwork for long-term change. Concerns were expressed about ensuring that the roadmap incorporates timelines for each stage of implementation, enabling stakeholders to approach the transition in a structured, phased manner. Suggestions included setting regular checkpoints to review progress and adjust as necessary to accommodate emerging scientific and regulatory developments.

Beyond the number of animals saved, it was highlighted that the success of the transition should also be measured by its impact on business, especially within the chemical sector, where industries are highly interconnected. Any changes could potentially lead to disruptions that need to be managed carefully. The importance of tracking the effects of these disruptions on businesses and SMEs, as well as fostering innovation, was emphasised. Transparency in how these challenges would be addressed was seen as critical, ensuring that the roadmap includes concrete actions to help mitigate negative impacts on SMEs and foster growth in innovation.

The conversation also recognised the critical importance of short-term actions, particularly those related to organisational structure and long-standing processes. The transition away from animal testing for chemicals will take time, and participants stressed the urgency of setting up the right structures and frameworks from the outset to avoid delays later in the process. Suggestions included setting up a programme for regular reviews of the roadmap to ensure it can adapt to evolving needs, as well as the importance of maintaining transparency in regulatory processes.

Aligning the transition away from animal testing with enhanced protection for people and the environment was another significant point raised. New approach methodologies must not only meet regulatory standards but also improve safety and environmental outcomes. The introduction of these methods should incorporate progress indicators that reflect better protection for both people and the environment. This was seen as essential to ensure that the transition results in tangible benefits beyond the reduction of animal testing.

A proposal emerged to define regulatory questions upfront to help guide the roadmap's development. The importance of a dialogue mechanism throughout pre-competitive and registration stages was discussed, with the aim of improving regulatory feedback. In addition, a staged assessment process was proposed, which could enable more effective engagement with regulators and provide a platform for building confidence in the new methodologies. From the pharmaceutical sector, there was an emphasis on the need for flexibility in regulatory guidelines for NAMs, as well as the importance of trust-building between method developers and regulators. Leveraging existing networks, including those in the pharmaceutical industry, was suggested as a way to ensure a smooth transition, especially considering the sector-specific needs and therapeutic modalities.

The session then moved toward discussing the practical aspects of implementing the roadmap. A key suggestion was the establishment of a cross-sector platform to facilitate collaboration, involving stakeholders such as the European Commission, regulatory bodies, industry

sectors, Member States, CROs, academic communities, and NGOs. The idea of creating an expert group to oversee the transition and support the application of new methods was also put forward, along with a coordinated validation and testing strategy to ensure consistency and reliability across sectors.

Education and training emerged as foundational components for a successful implementation. It was recognised that, for the roadmap to succeed, all stakeholders, especially SMEs, must be educated and trained on NAMs and non-animal testing frameworks. A concerted effort to improve professional education systems and engage SMEs through these systems was suggested as a way to ensure long-term stability and investment in the transition. Validation systems for new testing methods were also identified as crucial, with participants recommending the establishment of solid and reliable frameworks for validating alternative test methods to ensure their long-term viability.

Furthermore, the need to leverage existing networks and structures, such as international working groups, was discussed as a way to overcome obstacles to the wider adoption of new methodologies. Some NAMs are already in use, and the focus should be on addressing the challenges that currently prevent their broader implementation. Expert groups could play a vital role in identifying these obstacles and proposing solutions to overcome them.

The discussion then turned to the timelines for the roadmap's milestones. It was proposed that short-term actions should fall within three to five years, medium-term actions within three to ten years, and long-term actions beyond ten years. A key point raised was the importance of incentivising data sharing with regulatory authorities. Mechanisms such as the voluntary submission of data, informal dialogues, and the use of qualification criteria were suggested as ways to encourage collaboration and build trust between method developers and regulators.

"THE IMPROVEMENT OF MOVING AWAY FROM ANIMAL TESTING HAS TO GO HAND IN HAND WITH PROTECTION, THE IMPROVED ACCELERATION AND IDENTIFICATION OF HARMFUL CHEMICALS AND REDUCING HARM FOR WILDLIFE AND PEOPLE."

The session concluded with a summary of the key points raised throughout the discussion. The importance of collaboration, transparency, and continuous review was reiterated, highlighting how these elements would be essential to the successful transition to animal-free testing methodologies. Stakeholders were urged to remain engaged and continue refining the roadmap to ensure its successful implementation. Emphasis was placed on stakeholder engagement, transparency, and the need for regular reviews to adapt the roadmap to emerging needs and challenges.

Moving forward, the session's key recommendations revolved around tracking and managing disruptions, particularly for SMEs and innovation. Transparent mechanisms to monitor the impact on business and industry were considered essential for managing these disruptions. Establishing a robust organisational structure to support collaboration across sectors, alongside providing comprehensive education and training on NAMs and non-animal testing frameworks, were seen as crucial for a smooth transition.

Data sharing was another focal point, with participants advocating for systems similar to REACH to facilitate collaboration across substances and legislation. The need for regular, structured reviews of the roadmap was also emphasised to ensure that it remains relevant. Clear reporting and tracking mechanisms were recommended to monitor roadmap implementation and measure its impact over time. This transparency would allow for regular assessments and enable stakeholders to make adjustments as needed. Tracking data related to regulatory acceptance and NAM adoption rates could also provide valuable insights into the roadmap's effectiveness and identify areas where further support or adjustments are required.

The session provided valuable insights into the necessary actions and milestones for implementing a roadmap in response to the European Citizens Initiative. Through collaboration, transparency, and continuous adaptation, the roadmap can successfully drive the transition to animal-free testing, benefiting both human and environmental health.

Session 6: Closing Remarks

Participants

Kristin Schreiber (DG GROW)

Key Points

- The EU leads efforts in animal welfare, having invested over €1 billion in NAM-related projects in the past two decades.
- The roadmap provides clarity for stakeholders and enhances regulatory frameworks for non-animal testing.
- New methods promise competitive advantages and innovative research potential.
- Stakeholder engagement is critical, with further consultation opportunities planned for 2025.
- Mutual acceptance of data will support international alignment for animal-free testing.

The closing remarks reaffirmed the EU's dedication to phasing out animal testing in chemical safety assessments, highlighting the Union's longstanding commitment to animal welfare and ethical testing methods. Over the past two decades, the EU has invested over €1 billion in more than 300 research projects focused on developing NAMs, underscoring its leadership in this area. However, it was acknowledged that further efforts are required to fully eliminate animal testing.

The roadmap will act as a guiding framework for stakeholders, including industry, regulatory bodies, NGOs, and the research community, offering clear steps to achieve an animal-free testing paradigm. The session emphasised the potential benefits of adopting animal-free testing methods, which are expected to improve chemical safety assessments, increase industry efficiency, and enhance competitiveness. Despite the complexities in developing the roadmap, progress was recognised, with the roadmap expected to be published by the beginning of 2026.

Acknowledging the valuable contributions from participants, the speaker emphasised how these inputs will help shape the roadmap. Upcoming opportunities for continued stakeholder engagement were highlighted, including the 2024 EPAA annual conference focused on maximising the uptake of new methods under existing EU regulations, along with ongoing consultations through which stakeholders can share their views.

The importance of international collaboration was also emphasised, particularly in terms of mutual acceptance of data for chemical safety assessments. The active involvement of EU agencies in supporting the working groups on both animal and non-animal methods for chemical safety assessments was recognised as vital to the roadmap's development.

The active participation of attendees was acknowledged as key to the workshop's success, and it was noted that further engagement will continue as the roadmap progresses. The session concluded with an invitation to the next workshop, planned for mid-2025, and appreciation for everyone's contributions toward the shared goal of phasing out animal testing.

"THE ROADMAP WILL REALLY BE A FRAMEWORK THAT CAN PROVIDE GUIDANCE, MORE CLARITY, AND CERTAINTY FOR ALL ACTORS - AUTHORITIES, INDUSTRY, BUSINESSES, BUT ALSO, OF COURSE, THE RESEARCH COMMUNITY AND NON-GOVERNMENTAL ORGANISATIONS ON HOW TO MOVE FORWARD TOWARDS OUR COMMON OBJECTIVE."

Annex 1: Audience Suggestions and Feedback

A Slido poll, conducted during the conference, gathered insights from participants on various aspects of the roadmap to phase out animal testing. Participants were asked who should provide resources to manage the required validation efforts and were then asked to rate on a scale of 0 (low priority) to 5 (high priority), how important they consider the various elements of the roadmap.

The poll indicated that participants viewed the identification of short-term replacements for testing methods requiring animals as of medium priority (score 3), while developing new regulatory systems based only on animal-free information was seen as a high priority (score 5).

Asked whether they **consider the mutual acceptance of data (MAD) important**, most respondents agreed that mutual acceptance of data is essential, particularly to support international harmonisation, reduce redundant animal testing, and streamline regulatory processes. Respondents frequently noted that MAD helps prevent the need to repeat animal testing across different jurisdictions, thereby promoting animal welfare and enhancing efficiency. Some also highlighted that MAD is beneficial for industries operating globally, as it allows data generated using non-animal methods to be recognised internationally, saving both time and costs.

A few responses suggested a tiered or flexible approach to MAD, where mutual acceptance is encouraged but should not delay scientific progress or regional decision-making. A minority of respondents were cautious, citing potential drawbacks in making MAD a strict requirement, as it could slow innovation. Overall, MAD was widely supported as a way to harmonise standards, facilitate global collaboration, and promote the adoption of non-animal methods.

Asked in **which legislative areas do we absolutely need to have OECD-test guideline methods**, participants gave a wide variety of responses, with REACH, pesticides, chemicals, biocides and methods featuring more prominently.

Participants were asked **whether validation is a necessary aspect to be included in EU research projects**, with responses overwhelmingly supporting it as essential for ensuring the credibility, reliability, and regulatory acceptance of NAMs. Participants noted that validation bolsters regulatory and scientific credibility, helping to ensure NAMs are robust, reproducible, and applicable to real-world scenarios. Many emphasised the importance of including validation early in research to increase regulatory uptake, with suggestions to integrate this requirement into EU-funded projects.

To support validation, numerous respondents advocated for dedicated funding, proposing separate streams or grants to cover validation costs. Some expressed concern that typical EU project durations are too short for full validation, recommending a stepwise approach with initial “pre-validation” stages. A few participants questioned traditional validation methods, suggesting a need for a more flexible system that could accommodate NAMs without relying solely on conventional benchmarks. Proposals included standardisation as a potential alternative and involving contract research organisations (CROs) to ensure NAMs meet regulatory requirements from the outset.

While most responses favoured validation, a minority raised concerns about its costs and potential delays. Some argued for a “pre-validation” readiness level within projects and noted that frameworks like Weight of Evidence (WoE) or Integrated Approaches to Testing and Assessment (IATA) might be viable alternatives in specific sectors, such as pharmaceuticals.

Participants were asked **whether new non-animal approaches, including NAM-based IATAs or**

defined approaches, should follow OECD GD 34 requirements for validation. Most respondents generally supported GD 34 as a foundation, especially for achieving international regulatory acceptance, but called for adjustments to make the validation process more flexible and efficient.

Many agreed that GD 34 promotes scientific credibility, reproducibility, and regulatory acceptance, providing consistent standards for NAMs. However, some participants expressed concerns that GD 34 is too lengthy and rigid for newer methods, potentially slowing the adoption of innovative NAMs. They suggested that GD 34 could be updated to allow for a more agile approach, incorporating different validation tiers depending on each NAM's specific purpose.

A flexible, case-by-case approach was proposed, particularly for sectors like pharmaceuticals, which may benefit from tailored validation frameworks rather than a "one-size-fits-all" method. Respondents noted the ongoing revision of GD 34 and hoped the updates would streamline the process to better support scientific advances.

Suggestions for which available non-animal methods should be prioritised for validation or standardisation, including at OECD level, revealed human toxicity, and in vitro methods to be the most common non-animal methods proposed.

Regarding **who should provide resources to manage the required validation e□orts**, the European Commission, ECHA, the EU authorities, the OECD, Member States, industry, method developers and standard setting authorities were all frequently named.

Suggestions for organisational structures revealed a preference for a centralised hub, with the ECVAM website (67%) emerging as the most popular choice for hosting information on NAMs and their validation status.

Asked about the most important actions the roadmap should list, the respondents cited regulatory action, validation, and NAMS as the priorities. NAMs also featured highly in response to a question on necessary short-term actions, as did REACH and regulatory actions.

Participants in the poll proposed various structures to support the effective implementation of the roadmap actions for phasing out animal testing. A central coordinating body with representatives from regulatory agencies, Member States, industry, academia, and NGOs was frequently suggested to oversee the roadmap's implementation and ensure broad stakeholder involvement. Many respondents supported a structure with multiple components, including scientific advisory committees, working groups, and international collaboration units to provide specific guidance on validation, regulatory acceptance, and harmonisation.

Several participants highlighted the importance of global alignment with international organisations such as the OECD and bodies like the US FDA and ICCVAM. To streamline coordination, respondents recommended a project management office or a steering committee with representatives from across regions and sectors. Many also emphasised the need for an agile, science-focused framework that includes interdisciplinary task forces, particularly for areas like validation and change management that affect multiple sectors.

While some respondents suggested building on existing structures, others advocated for establishing an independent entity with legal and regulatory authority to lead roadmap actions effectively.

Participants rated the importance of proposed roadmap elements on a scale of 0 (low priority) to 5 (high priority). The highest priority was given to the identification of short-term replacements for animal testing methods, with an average score of 3.88. This was followed by support for a scientific advisory group providing non-binding advice on animal-free methods in regulatory processes, scoring 3.57. Establishing organisational structures to implement the roadmap and support the long-term shift to animal-free methods received a score of 3.45.

Other elements were rated as lower priorities. Developing new regulatory systems based solely on animal-free data scored 3.22. A scientific advisory group for prioritising the development and validation of animal-free methods scored 2.89, while focusing on the international introduction of animal-free methods was rated the lowest, with an average score of 2.69.

Annex 2: Conference Agenda

Session 1 **State of play of roadmap development (chairing: Katrin Schutte)**

9:00	5 min	Welcome and housekeeping	Katrin Schutte
9:05	10 min	Opening address	Paul Speight, HoU DG ENV
9:15	45 min	Progress made to-date on the development of the Roadmap and status report from the 3 Working Groups on • Human Health • Environmental Safety Assessment • Change Management	Katrin Schutte (DG ENV) Georg Streck (DG GROW) Elisabet Berggren (DG JRC)
10:00	30 min	Q&A (panel of the WG presenters to answer and discuss questions from the audience, also online)	Katrin Schutte Georg Streck Elisabet Berggren
10:30	20 min	Coffee break	

Session 2 **Contributions to Roadmap from stakeholders (chairing: Denis Mottet)**

10:50	15 min	PARC – Progress with NGRAroute Roadmap	Matthias Herzler (BfR, DE)
11:05	15 min	NGOs Animal welfare – Recommendations from June '24 roundtable	Julia Pochat (Eurogroup for animals)
11:20	10 min	Update on EPAA activities (overview ppt)	Gavin Maxwell (Unilever)
Poster Session and Lunchbreak			
11:30 – 13:00		Poster viewing and Lunch, Lunch served at 12:00	all

Session 2 **Contributions to Roadmap from stakeholders - continued**

13:00	Update from ASPIS* on ASPA workflow with case example	Sylvia Escher (Fraunhofer, DE)
13:15	Innovative Health Initiative (IHI) VICT3R - virtual control groups to reduce animal use in toxicology research	Ferran Sanz (Pompeu Fabra University, ES) Thomas Steger-Hartmann (Bayer)
13:30	Q&A (to answer and discuss questions from the audience)	Julia Pochat Matthias Herzler Gavin Maxwell Sylvia Escher Ferran Sanz

Session 3 **International Test Guidelines, Validation, Qualification and Standardisation (chairing: Georg Streck)**

14:00	60 min	Interactive panel discussion – (reference to pre-reading with more specific questions) • How can we accelerate the development of international guidelines to replace animal tests • How can validation, qualification and standardisation be steered and improved to accelerate phasing out animal testing	Jelle Vriend (RIVM, NL) Maurice Whelan (DG JRC) Katrin Schutte (DG ENV) Mounir Bouhifd (ECHA) Chantra Eskes (EFSA) Orla Moriarty (EMA) Kirsty Reid (EFPIA) Jay Ingram (HSI)
15:00	15 min	*Coffee break*	

Session 4 **Transitional Initiatives Concept – potential examples (chairing: Elisabet Berggren)**

15:15	15 min	Introduction to the concept of transitional initiatives – an action under the roadmap	Andrew Worth (DG JRC, virtually)
15:30	10 min	EFPIA	Kerstin Kleinschmidt-Doerr (Merck)
15:40	10 min	Cosmetics transition experience	John Chave (Cosmetics Europe)
15:50	10 min	CEFIC-LRI	Petra Kern (Procter & Gamble)
16:00	20 min	Q&A (to answer and discuss questions from the audience)	Elisabet Berggren Kerstin Kleinschmidt-Doerr Arianna Giusti Petra Kern

Session 5 **Stakeholder input on actions and milestones for the Roadmap (chairing: Katrin Schutte / Georg Streck)**

16:20	5 min	Brief introduction with reference to pre- read and questions	Georg Streck (DG GROW)
16:25	50 min	Discussion on key actions and milestones for the Roadmap with audience and panel What actions/milestones should be added in the RM?	Sonja Beken (MS, BE) Katia Lacasse (CEFIC) Gavin Maxwell (EPAA) Marco Corvaro (CropLife Europe) Caroline Bassoni (SME, Cosmed) Emma Grange (Cruelty Free Europe) Ninja Reineke (Chemsec)

Session 6 **Closing remarks (chairing: Georg Streck)**

17:15	10 min	Closing remark – HoU/Director	Kristin Schreiber Dir DG GROW
17:25	5 min	Wrap up – announcements - closing of WS	Georg Streck (DG GROW)
17:30		End of the conference	

Publications Office
of the European Union