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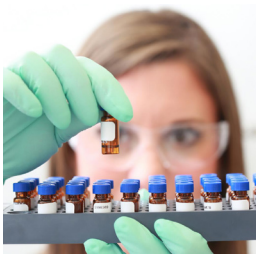
European Federation of Pharmaceutical Industries and Associations

# EFPIA Recommendations on Phasing Out Animal Testing for Chemical Safety Assessments

## JUNE 2025






# Executive Summary

Europe is at a pivotal moment in its journey toward phasing out animal testing in chemical safety assessments. Spurred by the success of the Save Cruelty Free Cosmetics European Citizens' Initiative and ongoing revisions to EU pharmaceutical legislation, the European Commission plans to produce a comprehensive roadmap by 2026. This roadmap will encompass a variety of sectors, including pharmaceuticals, which present unique challenges due to complex risk–benefit evaluations, global regulatory frameworks, and intellectual property constraints on data sharing. In parallel, proactive actions are taking place in other global regions.

EFPIA also proposes a 3-Basket Approach for prioritising and phasing out animal tests, distinguishing between those that can be ended immediately (Basket 1), those requiring moderate innovation and acceptance (Basket 2), and those that generate complex endpoints, for which feasible replacements are lacking (Basket 3).

The ultimate objective is to ensure patient safety and public health while fostering new approach methodologies (NAMs) and non-animal technologies (NATs) that are both scientifically reliable and globally recognised. Phasing out animal testing is an ambitious yet attainable goal, provided there is cross-sector collaboration, robust funding and incentives, global harmonisation, and streamlined regulatory acceptance of non-animal methods.

The European Federation of Pharmaceutical Industries and Associations (EFPIA), representing leading pharmaceutical companies in Europe who are at the forefront of actions on 3Rs and animal welfare. EFPIA has consolidated feedback and proposals into a set of pharma-specific recommendations relevant to chemical safety testing in particular, which aim to:

1. **Strengthen collaboration** between industry, regulators, academia, and non-government organisations (NGOs) through targeted consortia and incentives that catalyse new approach methodology (NAM) development.
2. **Improve data sharing** by creating safe harbour mechanisms, secure databases, and fee waivers for exploring novel methods.
3. **Update regulatory frameworks** to recognise the "last resort" principle, incorporate flexible qualification pathways, and align the roadmap with ongoing legislative revisions.
4. **Institutionalise regular guideline reviews** (e.g., every three years) to continuously phase out legacy animal tests and accelerate acceptance of new methods.
5. **Build public trust** by raising awareness of cutting-edge non-animal approaches that can yield superior, more human-relevant safety data.

# Introduction

## Legislative Momentum and External Drivers

In 2023, the European Commission announced its plan to develop a Roadmap to Phase Out Animal Testing for chemical safety assessments, building on the momentum of a high-profile European Citizens' Initiative. This roadmap will cut across all major regulatory frameworks—industrial chemicals, pesticides, biocides, and notably human and veterinary medicines. The Commission's announcement recognises the need to accelerate the adoption of new approach methodologies (NAMs)—including in vitro, in silico, weight of evidence approaches and other non-animal technologies—to enhance both ethical and scientific standards.

Concurrently, the EU is overhauling its basic pharmaceutical legislation. This legal revision offers a unique opportunity to embed stronger 3Rs (Replacement, Reduction, Refinement) provisions into the framework that governs drug development and authorisation.

Outside the EU, the U.S. FDA Modernization Act 2.0 and recent publication of their roadmap, Canada's Bill S-5, and other global reforms are likewise pushing for reduced animal testing and greater reliance on validated non-animal methods. The Commission's roadmap, therefore, must strive for international alignment, given that medicines often enter multiple markets.

Within the pharmaceutical sector, transitioning to non-animal approaches is both complex and potentially transformative. Unlike industrial chemicals regulated largely through hazard assessments, pharmaceuticals require risk–benefit evaluations, thorough analyses of dose-response relationships, and extensive clinical data. Moreover, global regulatory alignment remains a major challenge for industry adoption of non-animal methodologies:

- **Extended data requirements:** Before first-in-human trials, regulators require comprehensive non-clinical data to demonstrate safety and quality—historically reliant on animal testing.
- **Global harmonisation Needs:** Acceptance of novel non-animal approaches must extend beyond EU borders, otherwise drug developers risk performing certain animal tests to gain approval in other jurisdictions.

Bringing the pharmaceutical sector fully into a cross-sector roadmap to phase out animal testing for chemical safety testing requires acknowledgment of specific challenges and constraints. But it also holds unique opportunities for scientific innovation, as the sector already invests significantly in advanced in vitro testing and computational modelling.

To ensure the EU's upcoming roadmap reflects pharmaceutical realities, EFPIA recommends a targeted suite of 8 key actions, guided by a 3-Basket Approach. Taken together, these proposals strike a balance between ambitious elimination of outdated practices and a realistic path to ensure continued patient safety, globally.

# Pharma driven initiatives

Medicine developers are required to demonstrate that potential new and commercialised medicines, therapeutics and vaccines are effective and safe in humans, relying on many different technologies to support the most appropriate testing strategies, which include in assays, in silico methods, weight of evidence approaches and at a late stage, assays involving animals in preclinical development.

EFPIA and its members are committed to the science-based phase-in of methods to replace the use of animals for scientific purposes and the deletion of animal tests that are nowadays identified to be obsolete or redundant, although still required by some regulatory bodies. EFPIA companies aim to lead progress on this by engaging in a wide range of practical activities to help drive the development, uptake and promotion of NATs and NAMs so that these can be phased-in as soon as it is scientifically possible to do so.

EFPIA and its member companies have a long history of working to replace the use of animals in research. Examples of individual initiatives can be found in the EFPIA 3R brochures[1] which have been published 6 times since 2011. EFPIA is one of the founding members of the EPAA[2] – The European partnership towards alternative approaches to animal testing, which turns 20 this year. In 2023 EFPIA also hosted – together with RSPCA, UK's leading animal welfare organisation – a webinar[3] on "How the pharmaceutical industry is working to avoid and replace the use of animals for scientific purposes". We also joined forces with the HSI (now referred to as Humane World for Animals) and AFSA to host an international webinar to accelerate the global deletion of the abnormal toxicity test[4]. Furthermore, there are numerous actions on 3Rs as led by industry and regulators, including guidance from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[5] and on applications of NAMs for nonclinical safety assessment of drug candidates[6].

## The pharmaceutical industry members of EFPIA:

- Are fully committed to the principles of 3Rs;
- Continue to support the objectives of the Directive 2010/63/EU on the protection of animals used for scientific purposes which has enhanced animal welfare standards and mandated the application of replacement, reduction and refinement across the EU while ensuring Europe remains a world leader in biomedical research;
- Will continue to strive to go beyond what is legally required and work to develop and validate systems leading to improved 3Rs, animal welfare and high-quality science and technologies in everyday practice and ultimately improve the lives of the people and animals that stand to benefit from the research. Training of staff will remain an essential element of good science and good welfare;
- Are committed to continue invest in collaborative research initiatives and projects to improve animal welfare and 3Rs, and support start-ups with expertise in new approaches as we transition from the Innovative Medicines Initiative (IMI – the largest health public private partnership) to the new Innovative Health Partnership;
- Will continue to work with regulators, the scientific community and civil society to improve implementation of the science and speed up regulatory acceptance of alternative methods in the EU and at a global level;
- Will strive to lead by example by disseminating beyond own department and own establishment to drive improvements in welfare and general quality of science;
- Will improve the systems in place working with academia, CROs, animal breeding and testing facilities to share good practices, new methodologies and lead by example by uptake of high 3Rs and animal welfare standards in the daily activities;
- Will be transparent in telling what we do and how we do it, to explain and justify where live animals are required and used and also inform on the work and commitment of companies to reduce the sectors' reliance on animals;
- Will continue to identify, develop and implement their phase-in strategies and communicate on animal use through either dedicated webpages or CSR reports. Open communication and dialogue with the public are key to highlighting our contribution to phasing-in replacement methods.

1 https://www.efpia.eu/about-medicines/development-of-medicines/animal-use-and-welfare
2 https://single-market-economy.ec.europa.eu/sectors/chemicals/european-partnership-alternative-approaches-animal-testing_en
3 https://www.efpia.eu/news-events/events/efpia-event/how-the-pharmaceutical-industry-is-working-to-avoid-and-replace-the-use-of-animals-for-scientific-purposes/
4 https://pubmed.ncbi.nlm.nih.gov/35840492/
5 https://www.sciencedirect.com/science/article/pii/S0273230024001247
6 https://www.nature.com/articles/s41573-025-01182-9

EFPIA and its members have long supported public-private partnerships to advance science-based actions on animal welfare and the 3Rs, initially through the Innovative Medicines Initiative (IMI) and, since 2022, the Innovative Health Initiative (IHI). IMI projects have made significant contributions, involving industry, academia, SMEs, patients, and regulators. Notably, the IMI PREMIER[7] project developed a framework to prioritise the environmental assessment of existing medicines. Using a "Fish Decision Tree", it showed that fish testing could be avoided for about one-third of substances—potentially sparing over 250,000 vertebrates, saving €40 million, and reducing over 100 years of lab time. Launched in 2024, the VICT3R project[8] (VIrtual Control groups To reducE animal use in toxicology Research) focuses on reducing animal use in toxicology by developing Virtual Control Groups (VCGs)—a novel method that improves scientific outcomes while supporting the 3Rs and ethical testing. A future project aiming to launch under IHI is the BRIDGE project (Breakthrough Regulatory Innovation and Development throuGh sandbox Environments) which aims to enhance healthcare innovation in Europe by developing a comprehensive framework for designing and operationalising regulatory sandboxes. By addressing current regulatory limitations and engaging all stakeholders while ensuring compliance, the project seeks to create adaptable, fit-for-purpose methodologies that strengthen the regulatory ecosystem's capacity to promote healthcare innovation.

Phasing out the use of laboratory animals and phasing in of NAMs and NATs including in vitro models, in silico and weight of evidence is a significant and complex challenge. In order to initiate a change strategy, Merck KGaA[9] has developed a 3-Basket Initiative. EFPIA and its member companies have carefully reviewed this concept as an agile approach and a feasible starting point to break down animal replacement and identify redundancies into manageable elements. However, it should be noted, this approach would represent a first step in guiding animal replacement strategies for the clinical development of future medicines. Further actions by EFPIA members are outlined in the publication on the application of new approach methodologies for nonclinical safety assessment of drug candidates[10].

7 https://imi-premier.eu/
8 https://www.vict3r.eu/
9 https://www.merckgroup.com/en/sustainability/business-ethics/animal-ethics/our-approach-for-a-roadmap-to-phase-out-animal-testing.html
10 https://www.nature.com/articles/s41573-025-01182-9.epdf?sharing_token=rOCICtgIWZUwqAMavQ8yatRgN0jAjWel9jnR3ZoTv0O1CiwlfhhNEYCiHKGalbL7aSHS4tANzVrSGtemdhHJur24NnDF6yoVSoW5EAoQfsBfInxSNxtSkf-FTr_5c4jn7NiZQlw4SeY3dRBUj1TM6_yr8yN0Ik24PURrXdvK3iE%3D

# Pharma Sector-Specific Challenges and Opportunities

## Diverse Regulatory Pathways

Pharmaceutical developers must fulfil a host of requirements laid out in EU legislation, ICH and EMA guidelines, and international pharmacopoeias. Harmonising non-animal methods across these rules is time-consuming, particularly for those that generate complex endpoints (e.g., reproductive toxicity, carcinogenicity, or immunogenicity). Where the Commission can directly update legislation (e.g., EU directives), it still must engage internationally with bodies such as ICH or the International Medicines Regulators' Working Group on 3Rs to foster global recognition and mutual acceptance of data. Some specificities to take into consideration regarding the Hazard vs. Risk–Benefit:

- For industrial chemicals, the dominant principle is hazard-based thresholds.
- For pharmaceuticals, the decision-making process is more holistic, factoring clinical benefits against the potential for toxicity.
- This complexity can delay or complicate the elimination of an animal test if no equally informative NAM exists—or if acceptance across multiple jurisdictions is not guaranteed.

## Innovation, Intellectual Property, and Collaboration

**Innovation vs. Confidentiality:**

- Companies often discover and use advanced non-animal methods internally yet may be hesitant to publish or share data for fear that regulators may not accept novel NAMs—or that sharing data could compromise intellectual property. This can discourage early adoption.
- For the innovative pharma industry, data exclusivity and commercial trade secrets are essential for innovation.
- Large consortia like the Innovative Health Initiative (IHI), the European Partnership for Alternative Approaches to Animal Testing (EPAA), and other public–private partnerships can be vehicles to share the risk and cost of validating new methods. Enhanced incentives, dedicated funding, and a robust "safe harbour" approach would be beneficial.

**Data Sharing and Safe Harbour Environments**

A recurring theme in stakeholder feedback is the need for a trusted data-sharing platform—a "safe harbour"—that encourages sponsors to voluntarily submit novel NAM results without risking immediate demands for confirmatory animal tests.

- Adapting a new in vitro, in silico method or weight of evidence approach for regulatory acceptance is expensive and typically requires formal qualification or substantial bridging data. If sponsors receive fee waivers or other incentives, they are more likely to share performance metrics of their new methods, accelerating collective learning.
- Many companies hesitate to share negative or exploratory data on new approach methods if there is a risk of additional queries or duplicative requests for animal tests. A structured, standardised format (e.g., SEND for nonclinical data) could unify how results are stored and compared, avoiding duplication.

## Global Harmonisation

While the Commission can adjust EU legislation, worldwide acceptance is still needed for standard protocols. Pharmaceutical developers cannot simply adopt EU-accepted NAMs if the U.S. FDA, Japanese PMDA, or other authorities do not also accept them. Developers do not want to risk their global registrations by relying solely on a new approach that some jurisdictions do not accept. Joint outreach to ICH, WHO, pharmacopoeias, and other standard-setting bodies is essential to secure widespread agreement on non-animal test data.

Without global acceptance, companies risk "double testing"—using NAMs for EU submissions but reverting to traditional animal tests for other major markets. Consistency across regions is key to preventing partial adoption that undermines 3R goals. In addition, using and submitting different methods to various health authorities carries inherent risks. Animal models and NAMs often evaluate different parameters and possess unique specificity and sensitivity, which can lead to inconsistent results. These discrepancies may cause uncertainty, particularly among non-technical experts.

Global alignment requires sustained outreach to bodies like the IMWP (International Meeting of World Pharmacopoeias) and the new International Medicines Regulators' Working Group on 3Rs, may be beneficial in this aspect.

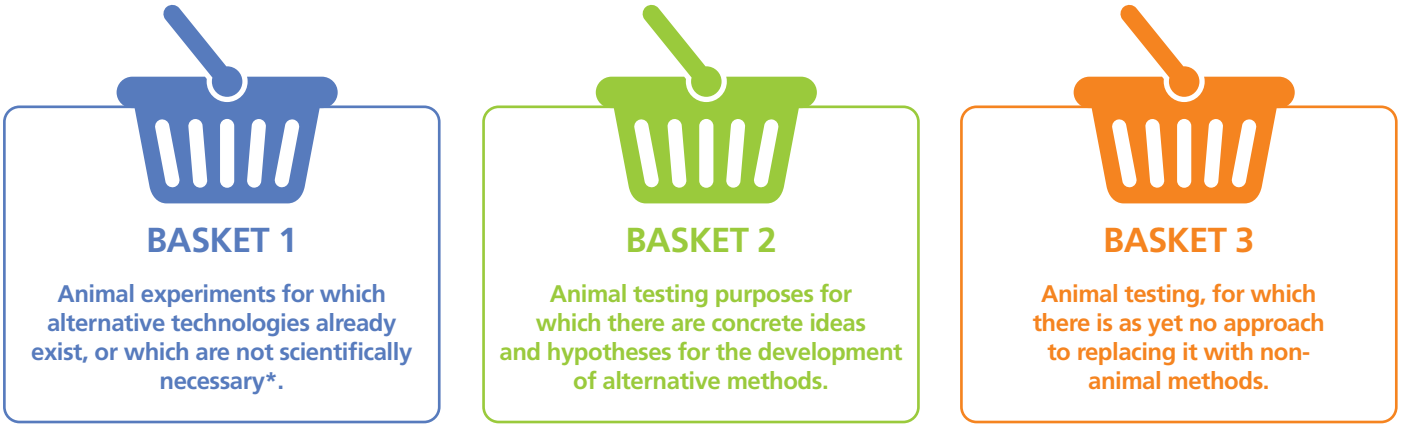
# The 3-Basket Approach: Pragmatic phasing out of animal tests

EFPIA aims to support the creation of the roadmap to reduce reliance on animal testing in the pharmaceutical industry. The EFPIA "3-Basket Approach" was developed to translate the general concept of phasing out animal testing into a practical, data-driven framework[11]. While there is no single replacement for animal testing, and various tests are required by legislation, we want to work together with all the stakeholders involved and drive forward phasing out of animal testing for chemical safety testing where scientifically feasible. For the roadmap to be ambitious yet practical, it must comprehensively reflect the current situation based on scientific, available solutions, and ongoing developments while prioritising human safety and scientific quality.

Recognising that no single alternative method can simultaneously replace every animal test, the approach aims to:

- Identify which types of studies are immediately replaceable with available technologies.
- Prioritise research and development where promising non-animal methods still require validation.
- Acknowledge areas where, for now, science does not yet provide a credible alternative.

To this end, we are engaging our members to sort the animal testing into three categories:




*also includes those animal experiments that are required by (individual) regulatory authorities or customers but which, in the opinion of those conducting them, would be scientifically dispensable.

The 3-Basket approach aims to demonstrate the current progress being made by the industry in the development of the effective use of alternative methods in drug development and testing in addition to supporting the EU Commission roadmap for phasing out of animal testing. However, the ultimate goal is not necessarily the simple like-for-like replacement of say one animal model with a non-animal alternative. There is opportunity to develop (non-animal, alternative) models with superior human-relevance (i.e., greater translational value) and improve human safety assessment. Adoption of non-animal methods will require redefinition of how human risk assessment is conducted and likely promote the evolution of clinical drug development paradigms.

EFPIA has piloted a 3-Basket Approach to categorise current animal tests used in the development of pharmaceuticals. Though different companies may have nuanced interpretations of specific tests, the aim is for our sector to clarify short-term elimination targets, medium-term R&D focus, and longer-term, more complex endpoints.

11 It is important to note that EFPIA engaged in the conceptual idea of 3-Baskets prior to the Commission identifying a similar approach to outline their roadmap approach – our Approach must not be confused with that of the Commission.

## BASKET 1 – Tests That Can Be Ended Now or Soon

Established non-animal methods already exist, or the test adds negligible scientific value. Any reliance on these tests tends to continue because of regulatory inertia, outdated monographs, or slow guideline revisions.

**Strategic Goal:** Removal from pharmacopoeias and regulatory requirements, globally. Leverage success stories (e.g., the rabbit pyrogen test replaced by the monocyte activation test) to demonstrate feasibility.

**Sample Tests:**

- Rabbit Pyrogen Test (RPT), replaced by MAT.
- Abnormal Toxicity Test (ATT) for some vaccines and biologics.
- Certain potency assays for which robust in vitro or cell-based methods exist.

**Implementation Priorities:**

- Remove them from guidelines, especially if they appear in compendial references.
- Work with regulators to gain acceptance worldwide (e.g., U.S. FDA, Chinese NMPA).

## BASKET 2 – Medium-Term Innovation Needed

Partial or emerging alternatives exist but are not yet fully validated, recognised by regulators, or comprehensive enough to replace the entire in vivo study type/duration. This category includes testing for certain aspects of pharmacokinetics, organ-specific toxicities, and immunogenicity, where partial in vitro/in silico models exist but are not fully validated for regulatory decisions. Often, these alternative approaches still need formal qualification or demonstration of real-world reliability.

**Strategic Goal:** Encourage collaborative R&D (e.g., public–private consortia), systematically collect data for method qualification, and incrementally reduce the scope or frequency of animal tests as the new methods mature.

**Sample Tests:**

- **Cardiovascular safety testing** where advanced in vitro assays (e.g., Comprehensive in vitro Proarrhythmia Assay (CiPA)) cover certain endpoints but not all.
- **Some organ-specific tox** (hepatotoxicity, nephrotoxicity, etc.) where microphysiological systems (MPS) or organ-on-a-chip are promising but not widely recognised as definitive replacements.
- **Immunogenicity/reactogenicity assays** where large-scale data sets and multi-lab validation are lacking.

**Implementation Priorities:**

- Targeted funding calls for method development, via Innovative Health Initiative (IHI) or other EU frameworks.
- Early scientific advice to regulators, culminating in Letters of Support or "safe harbour" data submissions.
- Enhance regulatory reviewer training and familiarity with novel in vitro, in silico, and microphysiological models.
- Develop user-friendly guidelines for method qualification to reduce duplication of effort.

## Basket 3 – No Current Replacement on the Horizon

Highly complex studies for which no clear scientifically valid in vitro or in silico solution has yet emerged. These typically involve multi-system or long-term biological processes that are not easily replicated in laboratory models (e.g., multi-generational reproductive toxicity, full carcinogenicity).

**Strategic Goal:** Invest in "moonshot" research—fundamental breakthroughs in AI, organ engineering, systems biology—that may eventually move these tests into Basket 2 or 1. In the meantime, minimise or refine these tests as much as possible under the 3R framework.

**Sample Tests:**

- Extended reproductive toxicity or multi-generation studies.
- Long-term carcinogenicity protocols.

**Implementation Priorities:**

- Harness broad-based consortia to push high-risk, high-reward scientific advances.
- Document all partial successes (e.g., refining or reducing the scope of studies) and channel them back into the regulatory pipeline.
- Establishment of regulatory frameworks to test novel methods in parallel with traditional studies.

**By organising tests into these baskets, EFPIA hopes to streamline the industry's engagement with regulators, accelerate the phase-out of obsolete tests, and focus investments and collaborative efforts where they are most needed.**

## Moving Forward: From Categorisation to Implementation

The EFPIA 3-Basket Approach is not a final or rigid classification. Instead, it is a living framework that will evolve as scientific capabilities, regulatory acceptance, and market realities shift. While the 3-Basket Approach helps structure internal industry planning, EFPIA envisions it as a collaborative tool shared with regulators and other stakeholders. Potential next steps include:

- Consideration of internal strategies to drive forward actions on the 3 baskets internally.
- Discuss at ICH or International Medicines Regulators' Working Group on 3Rs forums, presenting the baskets as a roadmap for sequential test eliminations.
- Host further multi-stakeholder workshops (involving the EMA, EDQM, ECHA, NGOs, etc.) to gather feedback, refine the basket definitions, and ensure broad acceptance of short-term vs. long-term priorities.
- Assign each basket or sub-category a set of key performance indicators (KPIs).
- Update these periodically in EFPIA's public 3R reports or in Commission progress updates.

By systematically applying this categorisation, we foresee an acceleration of the overall timeline for replacing animal tests and we can ensure that no test remains in routine use once its non-animal alternative is proven scientifically valid and gained regulatory acceptance. Through focused collaboration, continuous method qualification, and robust policy alignment, the 3-Basket Approach can help usher in a new era of ethical, scientifically advanced pharmaceutical development.

# EFPIA's Key Recommendations (to industry, researchers, regulators and decision makers)

Drawing on input from EFPIA member companies, NGOs, regulatory agencies, and ongoing Commission discussions, EFPIA offers the following 8-point framework for short- to medium-term implementation within the forthcoming roadmap on chemical safety testing. Where possible, these measures also set the stage for longer-term breakthroughs.

## Strengthen Collaboration and Incentives

1. **Public–private research**
    - Expand EU funding opportunities for NAMs.
    - Ensure multistakeholder consortia (academia, industry, regulatory bodies, NGOs) with well-defined metrics (e.g., the ALURES database, 3 basket approach) to identify priority tests and methods.
2. **Waive fees for NAM-specific scientific advice and qualification**
    - Encourage companies or developers to discuss and propose non-animal strategies early by removing fees for scientific advice or method qualification pathway specifically for NAMs.
    - Dedicate regulators with NAM expertise to guide applicants through acceptance processes.

## Improve data sharing and safe harbour

3. **Secure data-sharing Infrastructure**
    - Support robust platforms (e.g., IMI PREMIER for environmental risk assessment data) where sponsors can deposit data, including negative or neutral results, without jeopardising IP.
    - Incentivise submissions (e.g., GDP extensions or fee reductions) when sponsors provide non-animal method data.

## Update data requirements and boost regulatory flexibility

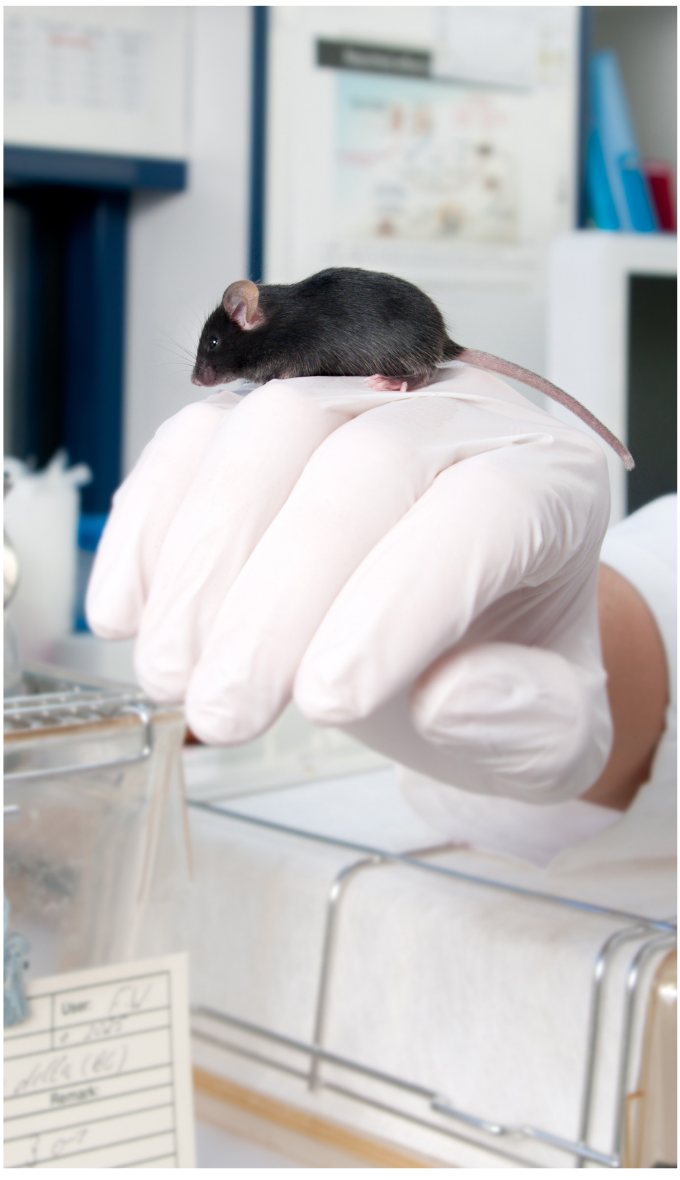
4. **Align Roadmap with revision of legislations**
    - Remove inconsistencies between new and revised legislation which contradict the goal to decrease animal testing.
    - Align legislation with the requirements of Directive 2010/63 on the protection of animals used for scientific purposes with the 3R principle in other chemical frameworks.
5. **Push for International Harmonisation**
    - Request to EMA to work towards expanding of the International Medicines Regulators' Working Group on 3Rs to also include other key regulators (e.g., China NMPA, India CDSCO).
    - Present a unified EU stance at ICH, WHO, and the International Meeting of World Pharmacopoeias for mutual acceptance of non-animal data.

## Foster Regular Guideline Updates and Method Qualification

6. **Review official test guidelines and encourage non-animal methods via reflection papers**
    - Create a systematic cycle (e.g., every three years) to review official test guidelines and identify which animal-based protocols can be replaced, streamlined, or removed. Build on the 3Rs guidance document and the reflection papers of the EMA on the current regulatory requirements for medicinal products for human use and for opportunities for implementation of the 3Rs.
    - Convene multi-agency workshops (EMA, EDQM, ECHA, EFSA) to gather external experts' input on new non-animal approaches.
    - Publish regulatory letters of support or Q&A documents explicitly endorsing in vitro or computational approaches for non-clinical efficacy data, mitigating reliance on routine in vivo proof-of-concept.
7. **Enhance qualification procedures**
    - EMA to consider hosting workshops to inform applicants on how to request official qualification of new in vitro and in silico methods (reducing reliance on case-by-case waivers).
    - Expand the Innovation Task Force (ITF) and national equivalents to handle NAM-specific queries more rapidly.

## Raise Public Awareness and Engage Stakeholders

8. **Drive Public Communication on Innovative Alternatives**
    - Leverage Joint Research Centre (JRC) reviews and industry best practices to highlight leading-edge technologies—organ-on-a-chip, advanced computational models, and microdosing.
    - In collaboration with patient groups and clinicians, communicate the scientific benefits of more human-relevant approaches to ensure public support.



# Roadmap initiatives where EFPIA is engaging

- EFPIA and our members have actively participated in the workshops organised by the Commission on the preparation of the roadmap to phase out of animal testing for chemical safety testing:
  - 1st Commission Workshop on 11th – 12th December 2023
  - 2nd Commission Workshop on 25th October 2024
  - 3rd Commission Workshop on 16th – 17th June 2025
- EFPIA participated in the various calls for information and data as part of the Commission's activities on the preparation of the roadmap to phase out of animal testing for chemical safety testing:
  - Call for Evidence was open 17th September – 15th October 2024 (91 contributions received)
  - 1st Targeted Consultation was open December 2024 – January 2025 (193 contributions received)
  - 2nd Targeted Consultation – Kicked off April 2025 (EFPIA is preparing a response)
- EFPIA follows the developments of the 3 working groups set up by the Commission on human health, environment, change management, having participated in a meeting with officials on the latter.

**Relevant roundtables and workshops:**

- November 23: Tarazona, J. V et al (2024) "Use of alternatives to animal testing for Environmental Safety Assessment (ESA): Report from the 2023 EPAA partners' forum", Regulatory Toxicology and Pharmacology, Volume 156, February 2025, https://doi.org/10.1016/j.yrtph.2025.105774
- June 2024: multi-stakeholder roundtable workshop was organised by five animal protection non-governmental organisations, Brussels ( Walder, L. et al (2025) "EU roadmap for phasing out animal testing for chemical safety assessments: Recommendations from a multi-stakeholder roundtable", ALTEX - Alternatives to animal experimentation. doi: 10.14573/altex.2503241.)
- November 2024: Science policy workshop on Leveraging innovative research tools to meet public health challenges: a BioMed21 (Pistollato, F et al (2025) Leveraging innovative research tools to meet public health challenges: a BioMed21 workshop report. NAM Journal Volume 1, 2025, 100023 doi.org/10.1016/j.namjnl.2025.100023)
- March 2025: Joint Commission/EPAA conference on Animal-Free Chemical Safety Assessment (AF-CSA) (final report being prepared)
- April 2025: Commission DG RTD workshop on NAMs future priority research areas, Brussels
- The RSPCA, working with Eurogroup for Animals has developed an overarching Action Plan to accelerate the transition to non-animal science in the pharmaceutical sector. It can be accessed via this webpage link: https://tinyurl.com/NAMsActionPlanPharma

  This document has been built on the understanding that many companies wish to incorporate activities into their work that contribute to the development, acceptance and uptake of non-animal methods and approaches - but have indicated that they would welcome and value additional ideas and practical guidance for how best they may do this. The aim of this Action Plan is to outline examples of specific key actions that individual pharmaceutical companies could undertake in a coordinated manner to review their own current practices and further accelerate the transition towards non-animal science for the development and testing of new medicines and vaccines.

  The Action Plan is not an exhaustive list of everything a pharmaceutical company can do, but it hopes to serve as a useful guide to inspire thought, review and action. Activities already taking place on this topic within and across companies should be seen as complementary and mutually reinforcing to those in this Plan. Companies are encouraged to adopt and adapt the Plan as they see fit according to their own situation, and to endorse, promote and share their efforts with others as appropriate.

# Conclusion and Next Steps

EFPIA and its members fully support a science-driven, stepwise phase-out of animal testing—one that upholds patient safety, accelerates innovative medicine development, and aligns with societal expectations. Achieving this requires:

- Political will to integrate robust 3R provisions into revised pharma legislation, setting a forward-looking standard that embraces NAMs.
- Regulatory innovation to accommodate new science quickly—through fee waivers, safe harbour processes, and targeted test guideline updates.
- Global outreach to ensure that EU leadership paves the way for internationally harmonized solutions.
- Resource infusion for collaborative R&D and large-scale validation studies.

Through its 3-Basket Approach and the recommendations above, EFPIA members stand ready to work with the Commission, Member States, regulators, NGOs, and academic partners to advance non-animal safety science without compromising the high standards that protect European patients and consumers.

EFPIA looks forward to further dialogue and concrete actions in the coming months as the Commission's roadmap takes shape, ensuring that pharmaceutical-specific challenges are not overlooked but proactively addressed. By combining strategic prioritization, global collaboration, and a clear policy framework, Europe can demonstrate global leadership in driving the transition away from animal testing in pharmaceutical safety assessment.

**Contact**

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https://www.efpia.eu/about-medicines/development-of-medicines/animal-use-and-welfare/

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