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COMMUNICATION FROM THE COMMISSION

Roadmap towards phasing out animal testing for chemical safety assessments

{SWD(2026) 144 final}

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1 INTRODUCTION

The European Union (EU) is firmly committed to phasing out animal testing at the earliest opportunity [1]. This policy goal recognises the need to protect animals as sentient beings [2]; it is not only an ethical imperative but also an opportunity for industrial competitiveness. Replacing animal testing, however, has proven to be challenging and overall progress is too slow (see Figure 1). Between 2015-2023, over 15 million animals have been used for testing for regulatory purposes in the EU, with almost 40% of them[3] for chemical safety assessments[4] [5].

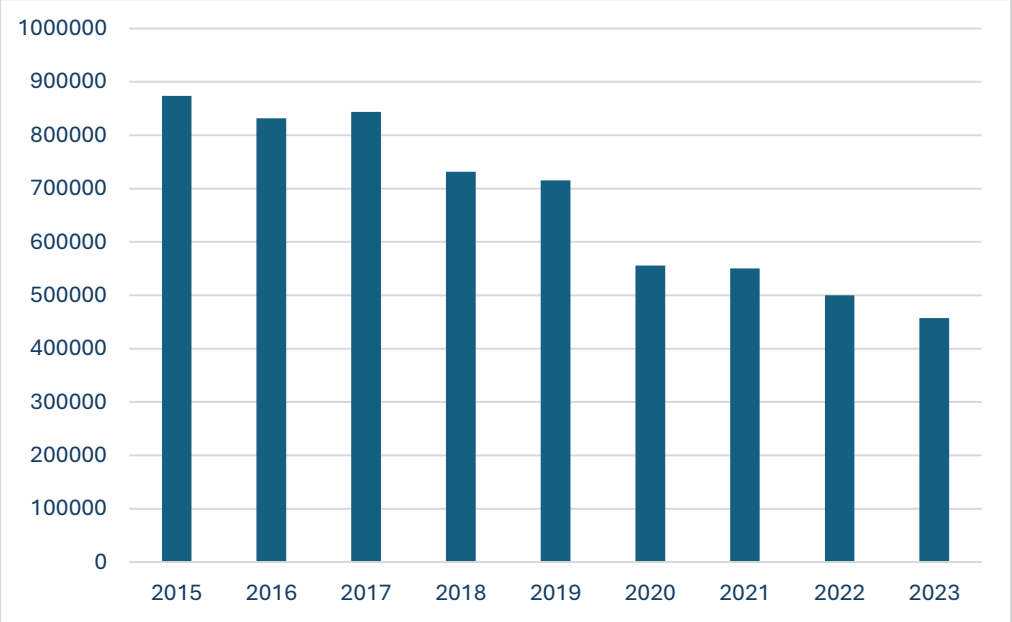


Figure 1: *Number of uses of animals for toxicity and other safety testing*

In 2023, in response to the European citizens' initiative 'Save Cruelty-Free Cosmetics – Commit to a Europe Without Animal Testing,' the Commission pledged to develop a

[1] Directive 2010/63/EU on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33) sets the goal of phasing out animal testing as soon as scientifically possible.
[2] Based on Article 13 of the Treaty on the Functioning of the European Union (TFEU).
[3] Most of the other 60% is for testing medicines that are not 'chemicals', but biological products like vaccines, antibodies, blood products, etc. that undergo both safety and efficacy testing.
[4] Data from: the ALURES (**A**nima**L** **U**se **R**eporting – **E**U **S**ystem) Statistical EU Database https://webgate.ec.europa.eu/envdataportal/content/alures/section2_number-of-uses.html; statistics are only available for protected life stages under Directive 2010/63/EU and for testing in the EU.
[5] In this document, the term "chemical" is used in a broad sense. In the context of food and feed safety assessment, it may include certain proteins, even if their evaluation may require **ad hoc methodologies** differing from those applied to conventional chemical entities.

comprehensive roadmap towards phasing out animal testing for chemical safety assessments [6]. Chemical safety assessments are used by companies to prove that their products, such as industrial chemicals, pharmaceuticals, biocidal or plant protection products are safe when they place them on the market. Such assessments involve scientific (eco)toxicological tests for different effects, and they are mainly animal tests. With new technologies, developed in recent decades or still under development, it will be possible to continue contributing to the phasing out of animal testing. Non-animal approaches have the potential to be more cost-efficient and faster, thus increasing competitiveness and shortening the time to market. Further development of non-animal approaches is also necessary to boost the innovation strength of industries for which a ban on animal testing is in place, like the cosmetics sector. In addition, the general public demands products that have been developed responsibly, without causing suffering to animals. The EU has been at the forefront of pioneering alternative methods. The Commission operates the EU Reference Laboratory on alternatives to animal testing as an integral part of its Joint Research Centre (JRC) [7]. Over the last two decades, the EU has provided close to EUR 1.5 billion in funding to research and has created one of the world's most advanced industries for alternatives to animal testing, from research-oriented entities to innovative laboratories, many of which are small to medium-sized enterprises. The global market for non-animal approaches is predicted to grow fast: *in vitro* toxicological testing, e.g., is expected to reach a market volume of up to EUR 30 billion and yearly growth rates of 12% by 2032 [8].

This roadmap interplays with several EU strategies supporting innovation on the 2024-2029 policy agenda and reinforces their joint impact. The **life sciences strategy** [9] aspires to make the EU more competitive by driving progress in areas such as healthcare, agriculture, food and biotechnology – where non-animal approaches will contribute to the safe and sustainable use of chemicals. The proposal for a **European Biotech Act** [10] aims to establish or reinforce the conditions for bringing biotechnologies from the laboratory to the factory. The **EU startup and scaleup strategy** [11], and the future **European Innovation Act** [12] will both support small, innovative companies by facilitating access to funding and removing barriers to their success. The proposed **European Competitiveness Fund** [13] will provide an integrated financial framework for EU investments in strategic sectors which will help strengthening Europe's innovation capacity, including for non-animal approaches. In the **Chemicals Industry Action Plan** [14] the Commission emphasises that innovation plays a crucial role in advancing chemical safety and announces the intention to publish this roadmap. Lastly, the voluntary **Safe and**

[6] C(2023) 5041: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023XC0818%2801%29&qid=1773663489800

[7] Zuang, V., Ahs Lopez, E., Baccaro, M., Barroso, J., Berggren, E. *et al.*, Non-Animal Methods in Science and Regulation - EURL ECVAM Status Report 2025, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/8549094, JRC145459.

[8] In-Vitro Toxicology Testing Market Size, Trends, Growth Report 2032.

[9] COM(2025) 525, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025DC0525&qid=1762330863739.

[10] https://health.ec.europa.eu/publications/proposal-regulation-establish-measures-strengthen-unions-biotechnology-and-biomanufacturing-sectors_en.

[11] COM(2025) 270, EUR-Lex - 52025DC0270 - EN - EUR-Lex; (2025) 138, EUR-Lex - 52025SC0138 - EN - EUR-Lex.

[12] https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/commission-seeks-feedback-future-european-innovation-act-2025-07-09_en.

[13] COM(2025) 555 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025PC0555.

[14] COM(2025) 530 EUR-Lex - 52025DC0530 - EN - EUR-Lex.

Sustainable by Design (SSbD) framework [15][16] guides innovation to design safe and sustainable lifecycles for chemicals and materials, encouraging non-animal approaches.

2 OBJECTIVES OF THE ROADMAP

This roadmap sets out the clear objective and concrete steps needed to **transition from traditional animal testing methods to innovative non-animal approaches**. At the same time, it maintains an unyielding commitment to preserve the integrity of safety evaluations, which ensure a high level of protection for human and animal health and the environment. **Non-animal approaches must deliver a level of protection equivalent to that of currently established methods**.

The roadmap is accompanied by a Staff Working Document (SWD(2026) 144) that lays out in detail the evidence base supporting the proposed actions. Those actions do not yet fully enable the transition across all areas and may need to be complemented by more actions as implementation progresses.

The roadmap envisages gradually **replacing all animal testing for chemical safety assessments across the EU** [17] [18]. It structures its recommendations across 15 legislative domains [19], spanning industrial chemicals, consumer products, pesticides, biocides, chemical pharmaceuticals [20], food and feed additives, and verification of medical device biocompatibility. Recognising the diversity in risk assessment procedures across sectors [21], the roadmap envisages a tailored implementation of the recommendations, adhering to legislative protocols within each domain. At the same time, it embraces the **One Health approach**[22] [23] to take a holistic and sustainable approach to chemical safety assessment.

The roadmap provides a guiding plan of actions structured across three pillars.

- **Pillar I** – It sets out pathways for **making change happen – towards phasing out animal use**, by streamlining the identification of regulatory needs and accelerating the development, validation, qualification, standardisation and application of non-animal approaches to fulfil these needs.
- **Pillar II** – By aligning institutional efforts and resources, the roadmap champions the EU's ambition to **keep Europe at the forefront of research and innovation** by

[15] Annex to the Commission Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials (2023).

[16] Safe and Sustainable by Design chemicals and materials – Methodological Guidance, JRC Technical Report, 2024. Abbate E. et al., Publications Office of the European Union, EUR 31942 EN.

[17] Except for final stages of safety testing of veterinary medicines in target animal species.

[18] Replacing all animal testing in line with Directive 2010/63/EU. This entails also replacing the use of non-protected life stages and invertebrates. The Directive is based on the 3Rs principle and prioritises replacing testing on more sentient beings like protected life stages of vertebrates. The roadmap therefore considers replacing the use of non-protected life stages and invertebrates as a longer-term goal.

[19] Including REACH, legislation on pharmaceuticals, plant protection products, biocides, food and feed additives and others. See full list of legislation in the SWD Annex I.

[20] Only chemical pharmaceuticals come under the scope; biologicals, vaccines, gene therapies; advanced therapy medicinal products and novel therapy veterinary medicinal products are excluded.

[21] For example, complex multi-constituents, nanomaterials and other advanced materials, materials of biological origin, etc.

[22] https://www.who.int/health-topics/one-health.

[23] One Health - Public Health - European Commission.

applying non-animal approaches. It will support the development of the regulatory required tools and an ecosystem of innovative businesses.

- **Pillar III** – The roadmap proposes a robust organisational framework for **working together in Europe and beyond**. The framework will facilitate the implementation of proposed actions and promote collaboration among EU Member States, various regulatory sectors and international partners.

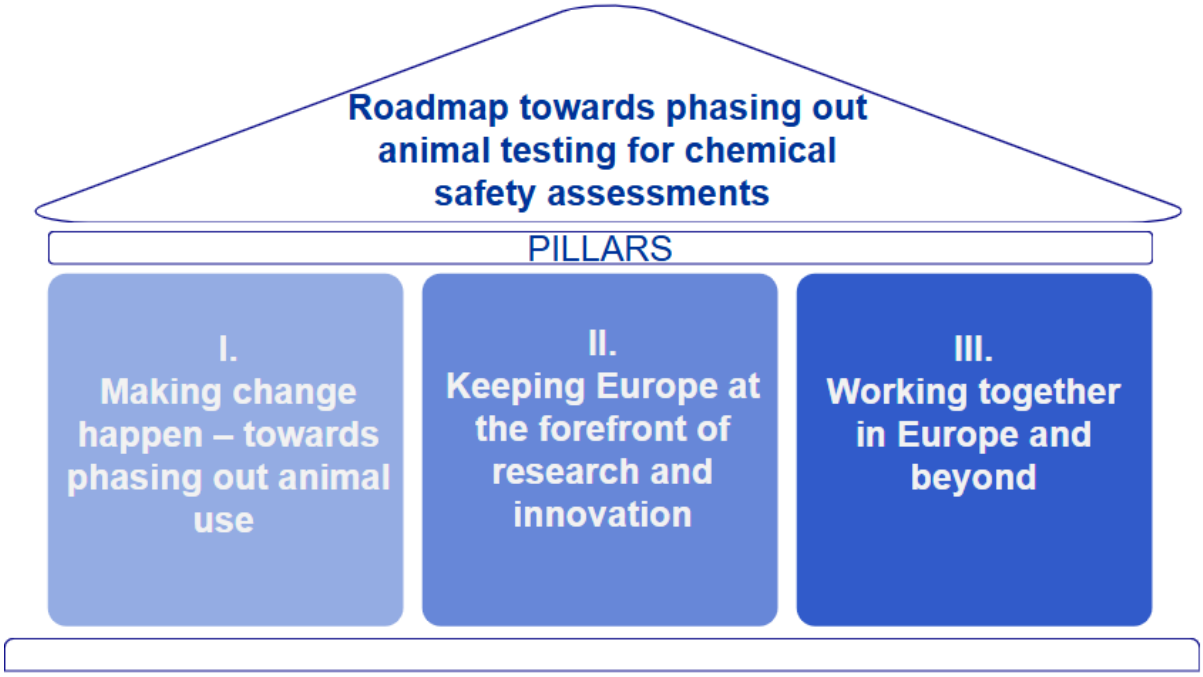


Figure 2: *Roadmap actions are structured according to three pillars*

3 ACTION TOWARDS PHASING OUT ANIMAL TESTING

3.1 Pillar I – Making change happen – towards phasing out animal use

3.1.1 Identifying opportunities towards phasing out animal use

Non-animal approaches refer to methods that fully replace the use of live animals [24]. While the roadmap aims to gradually phase out (i.e. fully **replace**) animal testing, both **reduction** and **refinement** remain important stepping stones along this path.

Definition of the Three Rs according to Article 4 of Directive 2010/63/EU
Replacement – a method or testing strategy not entailing the use of live animals.
Reduction – reducing the number of animals used in a project for a certain purpose without compromising the project's objectives.
Refinement – refinement of methods to eliminate or reduce pain, suffering, distress or harm to animals. The use of species with a potentially lower capacity to experience pain, suffering and distress (including early life stages of vertebrates or invertebrates) would thus result in refinement.

[24] The term NAMs (new approach methodologies) is purposefully avoided in this document (except where it is part of a project name) as many definitions exist and some of them still include the use of live animals.

3.1.2 Preparing for the transition to non-animal chemical safety assessments

Until recently, efforts to replace animal testing focused on achieving equivalent information through non-animal approaches. This was successful for specific regulatory endpoints, such as skin sensitisation, where the biological mechanisms are well understood. In such cases, the required information could be provided via a specific combination of non-animal methods.

For more complex endpoints, such as repeated dose toxicity or reproductive toxicity, it is widely acknowledged that developing replacements is highly challenging. Non-animal approaches yield different information from animal tests, requiring examination of different parameters from multiple methods to assess whether protection goals are met. As a result, both the methods and the overall safety assessment framework must change. The transition to a **new scientific framework** for integrating non-animal information represents a **paradigm shift.** Once developed and agreed, it will require revisions to some legislation governing chemical safety assessments or guidance. It also presents an opportunity to harmonise assessments across sectors consistent with the 'One Substance, One Assessment [25]' (OSOA) approach, whilst making of the future Common Data Platform on Chemicals a modernisation enabler.

A first proposed step is to outline a conceptual, overarching new scientific framework for the assessment of chemical safety [26]. Such framework will help to recognise knowledge gaps, prioritise future research funding and identify any needs for possible changes. Non-animal chemical safety assessments will mostly rely on a mechanistic understanding of toxicity rather than on observing adverse effects in animals. This entails determining whether molecular-level changes predict adverse outcomes, and can, if necessary, describe them quantitatively. In addition, from a One Health perspective, human health and environmental risk assessment should be more integrated. Non-animal approaches must deliver a **level of protection equivalent to that of currently established methods**, a core principle of this roadmap [27]. To achieve this, a future non-animal assessment framework should provide the information necessary to determine whether an 'adequate level of protection' (as defined by the regulatory context and problem formulation) for human health and the environment is attained. In general, an adequate level of protection represents a level of residual risk for which the combination of severity of effect and expected likelihood of occurrence is acceptable, or at least tolerable, from a societal risk-benefit perspective [28].

Some pieces of Union law have unique requirements for safety and efficacy testing in target animal species (e.g. veterinary pharmaceuticals). As such, they do not fall within the scope of

[25] The OSOA package consists of three pieces of legislation: (i) Regulation (EU) 2025/2455 of the European Parliament and of the Council of 26 November 2025 establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals; (ii) Regulation (EU) 2025/2457 of the European Parliament and of the Council of 26 November 2025 amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 as regards the reattribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals; and (iii) Directive (EU) 2025/2456 of the European Parliament and of the Council of 26 November 2025 amending Directive 2011/65/EU as regards the reattribution of scientific and technical tasks to the European Chemicals Agency.

[26] See the SWD, Chapter 2.2.1 'The long-term shift towards 'Next-Generation Risk Assessment' (NGRA) in EU chemicals legislation'.

[27] See also the suggestions for characterising this protection level outlined in the SWD, Chapter 2.2.2. 'Characterising the protection level and level of confidence associated with next-generation risk assessments'.

[28] See the SWD, Chapter 2.2.2, accompanying this Communication.

the roadmap. Based on the wide and complex regulatory and scientific ecosystem, there is the need for bespoke engagement with a representative spread of stakeholders to understand how they manage the significant change that the transition entails for their domains. Insights from social science research allow to analyse the dynamics of socio-technical transitions, thereby informing the change management towards phasing out animal testing.

3.1.3 Transitional initiatives – units of change in the roadmap's implementation

Stakeholders are carrying out or planning many activities that will help achieve the goal of phasing out animal testing in the regulatory assessment of chemicals. The Commission has set up a dynamic platform known as the **Catalogue of Transitional Initiatives** [29] to collect and showcase structured efforts contributing to this transition. It functions as a living repository, open to updates of ongoing initiatives and new submissions. Each initiative coherently describes activities, deliverables and intended outcomes, demonstrating how it contributes to the phasing out of animal testing [30]. The catalogue is also a guide to collaboration, since individual initiatives, or groups thereof, can serve as focal points for communities of practice.

3.1.4 Recommended actions for human health and environmental assessments

The roadmap provides concrete recommendations for the transition to non-animal approaches across all chemical safety assessment areas. These are organised into the actions listed below:

1. **Short-term actions** – available approaches for which the process of implementation into regulatory practice, including by omitting redundant tests, can be launched immediately or within a short timeframe.
2. **Medium-term actions** – approaches for which further steps for validation or regulatory adaptation are required. After finalising required steps, approaches will be implemented immediately when deemed acceptable for wider use in a given regulatory context.
3. **Long-term actions** – redefining scientific safety assessment frameworks and performance criteria for future non-animal approaches. Long-term actions include the need to develop further approaches, to be implemented in a given regulatory context when deemed acceptable. Work on a new scientific safety assessment framework will start immediately as a core activity for implementing this roadmap.

Tables 2 and 3 in the Annex provide an overview of the short-, medium- and long-term actions, with more details provided in the SWD [31]. Together with EU agencies, Member States and stakeholders, the Commission will continue identifying and refining actions enabling the transition.

3.1.5 Translating innovative methods into regulatory applications

Studies used for chemical safety assessment in the EU often follow test guidelines of the Organisation for Economic Co-operation and Development (OECD) or methods in the EU Test

[29] Joint Research Centre Data Catalogue - JRC Catalogue of Transitional Initiatives contributing to the replacement or reduction of the use of animals in the regulatory assessment of chemicals - European Commission.
[30] Worth A.P and Berggren E., NAM Journal, Volume 2, 2026, 100082, ISSN 3050-6204, https://doi.org/10.1016/j.namjnl.2026.100082
[31] See SWD (2026) 144 Chapters 3 and 4.

Methods Regulation [32]. ICH [33] guidelines and VICH [34] guidelines apply for human and veterinary medicines, respectively, supporting harmonised testing of safety, quality and efficacy. A third path for acceptance of methods is the standardisation process of the International Organisation for Standardisation (ISO) or the European Committee for standardisation (CEN), notably for medical devices [35]. In some legislative areas, qualification of methods in a specific use context plays an important role [36]. This system has advantages for both regulators and industry, providing legal certainty and ensuring efficiency in the assessment of the generated information and the reuse of data between sectors and different international jurisdictions. Insufficient funding for validation or standardisation studies has emerged from the stakeholders' consultations as an obstacle to the uptake of such methods [37]. Furthermore, a better prioritisation of the development of methods for validation, qualification and standardisation based on actual regulatory needs could help accelerate their adoption. The Commission will therefore introduce a **3-step mechanism** that systematically and transparently identifies the **key areas of regulatory needs for alternative approaches to animal testing** in all legislative areas in the scope of this roadmap.

1. Regulators are best placed to determine which information is needed to ensure that alternative approaches effectively fulfil the protection goals set out in the respective legislation. Agency collaborative structures[38] play a key role in gathering feedback from Member State and agency experts in the different legislative areas.
2. The Roadmap Steering Team[39] will compile the regulatory needs in a report [40].
3. The report will inform the Commission OSOA expert group, which is best placed to consolidate input from different sectors on regulatory needs for method developments in different areas.

The report will inform the Commission, Member States and stakeholders on how to prioritise the development of approaches and methods for validation, qualification and standardisation.

3.1.6 Regulatory exploration spaces and safe spaces

Safe spaces and regulatory exploration spaces can improve regulatory predictability, promote

[32] REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[33] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) https://www.ich.org/.

[34] International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) https://vichsec.org/.

[35] Another example is organ-on-a-chip technology, for which a standardisation roadmap was set up by the European Commission (Setting out a roadmap for standardisation of organ-on-chip technology - European Commission).

[36] E.g. in the pharmaceutical and food sector, see Qualification of novel methodologies for medicine development | European Medicines Agency (EMA) or EFSA's NAMs4NANO project (GP/EFSA/MESE/2022/01) https://www.efsa.europa.eu/en/news/nanotechnology-promoting-uses-new-assessment-methods

[37] https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/roadmap-towards-phasing-out-animal-testing_en.

[38] see chapter 3.3.3. Engaging Member State and stakeholder experts in collaborative structures

[39] See chapter 3.3.2 Roadmap Steering Team

[40] E.g. presented as a summary in the form of a Commission staff working document

and de-risk innovation, and accelerate the transition towards non-animal safety assessment by fostering collaborative learning.

Safe spaces are platforms that allow applicants to share data confidentially with regulators to explore the possible acceptability of specific, alternative methods for a given case. They enable non-binding exchanges to explore the acceptability of alternative approaches without regulatory consequences. They foster open dialogue and mutual understanding while reducing the perceived risk of early engagement.

Regulatory exploration spaces are informal, multi-stakeholder settings bringing together regulators, industry, academia and non-governmental organisations (NGOs) to discuss scientific and technical aspects of alternatives to animal testing, identify data gaps and co-develop solutions.

Among the decentralised EU agencies, the European Medicines Agency (EMA) provides the most advanced model aligned with the safe-space concept through initiatives such as the Innovation Task Force, voluntary data submission ('safe harbour'), scientific advice and qualification procedures. The European Food Safety Agency [41] (EFSA) and the European Chemicals Agency (ECHA) offer general pre-submission and helpdesk support but lack mechanisms to provide scientific advice on alternative approaches or exploratory dialogue on their regulatory applicability. The Member State Committee (MSC) of ECHA created by the REACH Regulation [42] has the legal framework and the mechanism [43] to take into account the availability of alternatives to animal testing [44] when deciding on a testing proposal.

Action points on pillar I - Making change happen – towards phasing out animal use

Replacing, reducing or refining animal testing in the short- to long-term

- Support the implementation of **over 30 targeted recommendations** to replace, reduce or refine animal testing in the short- to long-term as listed in the Annex (Table 2 and 3).
- Invite EFSA and ECHA to **organise a workshop in 2026** to support the implementation of actions for the **pesticides and biocides** area [45].

Supporting the change

- Provide **access to the experimental facilities of the JRC EU Reference Laboratory for alternatives to animal testing– support companies** that need to test, scale and validate alternative-approach-related products.
- Promote and update the **dynamic Catalogue of Transitional Initiatives**.
- **Use insights from social science research** to support the necessary change management.

Identifying regulatory needs - Supporting validation, qualification and standardisation

- Introduce a mechanism to **identify regulatory needs** for alternative approaches to

[41] See e.g. EFSA Catalogue of support initiatives during the life cycle of applications for regulated products https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472

[42] See recital 64 of REACH Regulation (EC) No 1907/2006.

[43] E.g. submission period for scientific information to prevent unnecessary animal testing.

[44] E.g. including existing data from similar substances.

[45] Workshop on implementing EC Roadmap on phasing out animals in pesticides and biocides | EFSA

animal testing.

- Provide information about options for **funding of validation, qualification or standardisation** of non-animal approaches.
- Continue encouraging the **preparation and updating of EU and international standards** [46] on non-animal approaches.
- Work to **make the formal validation procedure more effective and efficient** by:
  - leading on the revision of OECD Guidance Document 34;
  - working with the national contact points (NCPs) under Directive 2010/63/EU to optimise both the EU Network of Laboratories for the validation of alternative methods [47] and the Member States Network for Preliminary Assessment of REgulatory RElevance (PARERE), coordinated by the JRC EU Reference Laboratory.

Regulatory exploration spaces and safe spaces

- Organise a **workshop on EU experiences with both the regulatory exploration and the safe-space model** supporting implementation of such mechanisms.
- Explore the possible creation of a **regulatory exploration space at EFSA** for the qualification of non-animal approaches, starting with nanomaterials risk assessment.
- Strengthen efforts to accept **animal testing under REACH** only as the **last resort.**

3.2 Pillar II – Keeping Europe at the forefront of research and innovation

3.2.1 Continuing **investment in research and development**

As part of its commitment to phasing out animal testing, the Commission recognises the need to remain at the forefront of research and innovation on non-animal approaches. It also recognises the importance of translational strategies, converting research into novel testing approaches that provide robust and reliable safety data [48].

Artificial Intelligence (AI) will play an important role in reaching the goals of this roadmap. Non-animal approaches are increasingly being developed with or supported by AI tools. There are thus clear synergies between this roadmap, the **EU Apply AI strategy** [49] and the **AI in science strategy** [50] that will accelerate the uptake of AI across diverse scientific domains. AI applications range from functioning as an alternative to animal testing and enabling knowledge discovery to accelerating evidence synthesis and supporting collaborative research.

Human-relevant data are important for the development of non-animal approaches. The secondary use of personal electronic health data, provided in the **European Health Data Space**

[46] Harmonised standards like those developed by CEN or ISO as European and international standardisation organisations, respectively

[47] https://joint-research-centre.ec.europa.eu/projects-and-activities/reference-and-measurement/european-union-reference-laboratories/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/alternative-methods-toxicity-testing/european-union-network-laboratories-validation-alternative-methods_en

[48] See also SWD (2026) 144 Chapter 5.5. 'Translating innovative methods into regulatory applications – validation, standardisation, qualification'.

[49] https://digital-strategy.ec.europa.eu/en/policies/apply-ai.

[50] https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/artificial-intelligence-ai-science_en.

Regulation [51]**,** could become a relevant way to obtain human-relevant data. Under the **European Virtual Human Twins Initiative** [52], the roadmap will examine how human data and computational modelling can support chemical assessments.

Significant EU-funded research on technologies supporting the phasing out of animal testing is already under way. A **workshop on funding opportunities for new approach methodologies** organised by the Commission in April 2025 suggested, as priority areas for innovation, domains with high levels of animal use or where animal tests show limited human relevance. The discussions informed a **Horizon Europe topic** on non-animal approaches (EUR 49 million of EU support) under the 2026-2027 work programme, as announced in the life sciences strategy.

European research partnerships and projects, such as ASPIS [53], PARC [54] and NAMWISE [55], are generating recommendations, tools, practical guidance and training to promote the validation, integration and regulatory uptake of non-animal approaches.

These activities are strengthened by industry-driven initiatives, coordinated through CEFIC-LRI [56], ECETOC [57], the International Collaboration on Cosmetics Safety [58] (ICCS) and by sectoral associations such as EFPIA [59] and Animal Health Europe [60] for pharmaceuticals. The EPAA, a long-standing public-private partnership, provides a platform for cross-sector knowledge exchange, confidence building and data sharing [61].

The Commission will continue investing in research and development and strengthen synergies to facilitate the uptake of non-animal approaches through the **European Research Area policy action on new approach methodologies**[62]**.** The action brings together relevant stakeholders from the public, private and non-governmental sectors to align EU, national and regional policies to accelerate the development, validation, acceptance and uptake of non-animal methods for biomedical research, medicinal products and medical devices.

3.2.2 Cultivating an industrial ecosystem to bring non-animal approaches to the market

Growing economic interest in innovative biotechnology, including non-animal approaches for chemical safety assessment, is an important driver for progress.

The market for cell-based technologies is projected to reach **EUR 26.5 billion by 2028,** with

[51] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance), PE/76/2024/REV/1, OJ L, 2025/327, 5.3.2025.

[52] A virtual human twin (VHT) is a digital representation of a human health or disease state. https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins.

[53] Aspis – Project cluster for Implementation of novel Strategies.

[54] Partnership for the Assessment of Risks from Chemicals | Parc.

[55] https://namwise.eu/.

[56] Cefic-Lri – Long-Range Research Initiative.

[57] Home - ECETOC.

[58] ICCS - Advancing Animal-Free Safety Assessments for Cosmetics.

[59] efpia-recommendations-on-phasing-out-animal-testing-for-chemical-safety-assessments.pdf.

[60] AnimalhealthEurope.

[61] Many research and development efforts are described in the annual status report of the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM), https://link.europa.eu/qxKQxv.

[62] https://european-research-area.ec.europa.eu/sites/default/files/documents/2025-02/COM_2025_62_F1_PROPOSAL_FOR_A_RECOMMENDATION_EN_V5_P1_3951028.PDF.

the EU expected to capture around 30% of the global market share [63]. While the EU remains a leader in developing *in vitro* biotechnologies, it faces challenges converting scientific discoveries into business creation and global competitiveness within a rapidly growing international market [64].

To support this, the European Innovation Council has included an **Advanced Innovation Challenge** dedicated to new approach methodologies in its 2026 work programme [65]. In the **life sciences strategy**, the Commission commits to identifying and promoting collaboration opportunities between EU biotech clusters, with a focus on scaling up innovative companies and strengthening the EU's industrial innovation standing. This should build on existing actions such as the **European Cluster Collaboration Platform** [66] and align with the **EU startup and scaleup strategy**, including its **Charter of Access** for industrial users of research and technology infrastructures. The forthcoming **European Innovation Act** will further facilitate the access of innovative companies, with legislative measures planned for 2026.

Action points on pillar II - Keeping Europe at the forefront of research and innovation on alternatives

- **Accelerate research and development** of non-animal approaches through
  - maximising synergies through the European Research Area policy action announced in the life sciences strategy;
  - the European Innovation Council Advanced Innovation Challenge;
  - a Horizon Europe call [67] on non-animal methodologies for biomedical research and regulatory testing;
  - the launch of a matchmaking strategic interface to connect life science start-ups, industry and investors, to help alternative-approach-related start-ups reaching the market.
- **Enable AI to support the roadmap**:
  - accelerate the integration of AI-based tools into relevant roadmap actions;
  - support researchers and innovators developing non-animal approaches to navigate the EU regulatory landscape via the AI-powered interactive tool developed under the life sciences strategy [68];
  - an ongoing Horizon Europe call on generative AI in biomedical research.
- **Evaluate synergies with the European Health Data Space** Regulation to leverage human-relevant data for non-animal approaches.

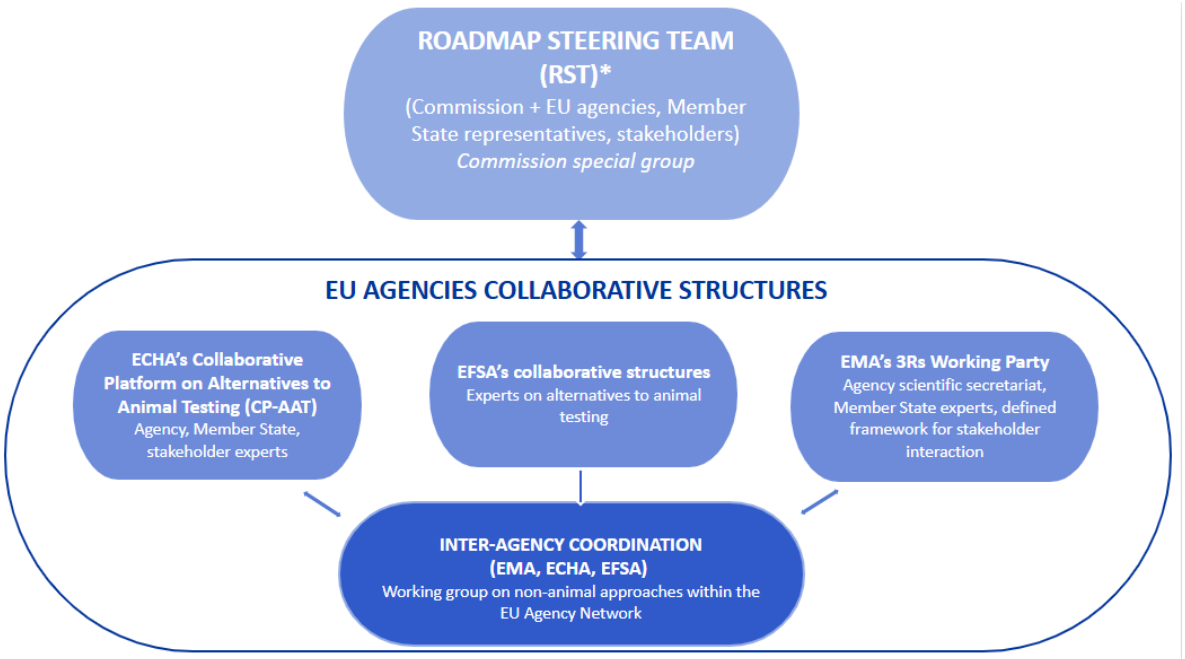
[63] 'In vitro toxicology testing market - Global forecast to 2028' https://www.marketsandmarkets.com/Market-Reports/in-vitro-toxicology-testing-market-209577065.html.
[64] Strengthening the competitiveness of EU in vitro biotechnologies - ScienceDirect.
[65] European Innovation Council - European Innovation Council.
[66] Clusters | European Cluster Collaboration Platform.
[67] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/horizon-europe-work-programmes_en.
[68] COM(2025) 525, EUR-Lex - 52025DC0525 - EN - EUR-Lex.

3.3 Pillar III – Working together in Europe and beyond

3.3.1 Working together with stakeholders

To guide the implementation of the described actions, whilst ensuring cohesion and cross-fertilisation between all relevant stakeholders, and to possibly develop further actions to move towards the goal of phasing out animal testing, it is proposed to set up the organisational structures as outlined in Figure 3, entailing a **Roadmap Steering Team**, **collaborative structures linked to EU agencies** and an **inter-agency working group of EU agencies**.

The development of this roadmap was accompanied by various activities enabling Member States and stakeholders to contribute. The Commission considers the continued collaboration with them essential for its sound implementation. Therefore, the Roadmap Steering Team and the **EU agencies' collaborative structures** include opportunities for stakeholders to get involved. This exchange will foster a common understanding of how to reach the goal and how to manage the significant change the roadmap represents. Stakeholder involvement is further strengthened through **transitional initiatives**. The roadmap will also promote engagement with the general public (see section 3.3.7).



*RST action teams will be set up as sub-groups if needed, with the option of stakeholder participation

Figure 3: *Proposed governance model for the implementation of the roadmap*

3.3.2 Roadmap Steering Team

With a view to secure an effective and inclusive steer for the roadmap implementation, the existing interservice group consisting of Commission services, with participation of the EU agencies ECHA, EFSA and EMA, will get expanded to form a **Roadmap Steering Team**, which will offer seats to committed stakeholders (Member States, industry, NGOs and academia). This team will regularly meet and provide the strategic steer to make the transition happen. It will ensure coordination between the other organisational structures supporting the

roadmap's implementation. It will also activate the members' own networks and engage with other initiatives to ensure widespread active involvement in implementation. If needed, the Commission will set up action teams to assist the Roadmap Steering Team in advancing particular action points. Stakeholders can be invited to an action team and will be selected according to the Commission's rules [69].

3.3.3 Engaging Member State and stakeholder experts in agency collaborative structures

Agency collaborative structures (e.g. agency expert groups or platforms), involving Member States and stakeholders, are key in providing advice on how to use non-animal approaches in a regulatory context. They should also help identifying key areas of regulatory needs and support prioritisation. Input on regulatory needs guiding the development of alternatives to animal testing is indeed crucial for accelerating their use. EFSA and EMA are already successfully using such collaborative structures [70] and ECHA announced the formation of a collaborative platform to promote the use of non-animal approaches in all legislative areas under its responsibility. The collaborative platforms will work closely with the Roadmap Steering Team to secure a coordinated implementation.

3.3.4 Increasing EU agency collaboration via an inter-agency working group

The exchange of good practices between EMA, ECHA and EFSA to promote the use of alternative methods in their regulatory fields is essential for a coordinated and coherent implementation across different pieces of Union legislation. An inter-agency working group, consisting of EMA, ECHA and EFSA, will formalise the already ongoing cooperation on alternative approaches and facilitate a regular inter-agency coordination.

3.3.5 International collaboration and alignment

Companies required to submit data for chemical safety assessments operate in an international environment with differing jurisdictions, with countries outside the EU replacing animal testing at varying speeds. Alignment and regulatory acceptance for alternative approaches at international level is thus crucial. The Commission and its EU agencies **already maintain a large international collaboration network** [71]. The Commission will **strengthen cooperation** by making the results of its work under the roadmap available to partner countries and international organisations. Alternative approaches that address regulatory needs will be proposed for recognition as international standards, through OECD test guidelines [72], or inclusion in (V)ICH guidance [73]. The Commission will also actively advocate for the integration of non-animal approaches into the Globally Harmonized System of Classification

[69] Commission Decision C(2016) 3301 establishing horizontal rules on the creation and operation of Commission expert groups.https://eceuropaeu.sharepoint.com/sites/expert-groups/Shared Documents/Forms/AllItems.aspx?id=/sites/expert-groups/Shared Documents/guidelines-on-the-implementation-of-the-horizontal-rules.pdf&parent=/sites/expert-groups/Shared Documents

[70] See SWD Annex II 'Ongoing agency activities that support the phasing out of animal testing for chemical safety assessments'.

[71] See SWD Annex II 'Ongoing agency activities that support the phasing out of animal testing for chemical safety assessments'.

[72] The principle of mutual acceptance of data (MAD) allows for the acceptance of data generated under good laboratory practice and following OECD technical guidelines.

[73] Supporting international uptake and use by pharmaceutical developers.

and Labelling of Chemicals (GHS).

3.3.6 Engaging with the general public to bring about change

There is strong support from the general public for phasing out animal testing, as demonstrated by the European citizens' initiative [74] that gathered more than 1.2 million signatures. Promoting public participation when implementing the roadmap will contribute to the resilience and quality of European democracy. Engagement with the public helps to build trust in science and evidence-informed policy while mitigating the influence of misinformation[75]. Policy makers are better equipped to address complex issues by taking into account people's expectations [76]. Engagement with the public can also bring about change by sparking curiosity in relevant educational opportunities and by informing consumer choices.

3.3.7 Training

Stakeholders highlighted the importance of tailor-made training on alternative and non-animal approaches. Offering such tailor-made educational resources requires the active engagement of many interested parties, including EU agencies and Member States.

Action points on pillar III - Working together in Europe and beyond:

- **Set up a governance structure** to support the roadmap implementation consisting of
  - A **Roadmap Steering Team**;
  - **Collaborative structures** at the agencies with Member State and stakeholder participation;
  - An **inter-agency working group** (EFSA, EMA, ECHA) within the EU Agency Network.
- Introduce a mechanism to **identify regulatory needs** for alternative approaches to animal testing.
- Continue to actively promote the **acceptance of non-animal approaches in international fora**.
- Create an **electronic information hub** to promote engagement with stakeholders and the general public to facilitate access to information on non-animal approaches.
- **Map existing training resources** provided by the Commission and EU agencies.

3.4 Indicators for monitoring progress – managing change by measuring it

A core parameter for monitoring progress towards the phasing out goal is the number of animals used for chemical safety testing. Figures for animal use within the EU are already published by the Commission in accordance with Directive 2010/63/EU [77].

A first set of core indicators grouped into four areas is presented in Section 6 of the SWD (2026) 144:

[74] https://citizens-initiative.europa.eu/initiatives/details/2021/000006_en.
[75] See also SWD (2026) 144 Annex III.
[76] Commission Recommendation on promoting the engagement and effective participation of citizens and civil society organisations in public policymaking processes eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:C(2023)8627.
[77] https://environment.ec.europa.eu/topics/chemicals/animals-science/statistics-and-non-technical-project-summaries_en.

(i) **engagement indicators** aim to capture public awareness and support, knowledge sharing, collaborations and partnerships;
(ii) **status indicators** relate to development and validation of non-animal approaches, funding and investment, cost-effectiveness, industry adoption and regulatory acceptance;
(iii) **counter-progress indicators** aim to identify barriers to acceptance and regulatory uptake, efficiency and reliability;
(iv) **progress indicators** are directly related to the ultimate aim of the roadmap, i.e. phasing out animal testing.

The Commission will assess the need for further indicators across all three pillars based on the work started during the roadmap's development [78].

Action points on monitoring progress and reporting:

- Develop an **indicator framework** to monitor progress on implementing the roadmap.
- Aim to obtain **data on animal use** for chemical safety assessments **outside the EU** used for the purposes of EU legislation.
- Regularly **report on the implementation status** of roadmap actions **through a public dashboard**.

4 CONCLUSIONS

With its response to the European citizens' initiative 'Save Cruelty-Free Cosmetics – Commit to a Europe Without Animal Testing', the Commission announced the development of a roadmap towards phasing out animal testing for chemical safety assessments. This roadmap sets out a strategic vision for a future in which the regulatory safety testing of chemicals ensures the protection of human health and the environment without relying on the use of animals. It:

- Outlines 22 concrete actions to drive the transition, complementing other strategic initiatives of the Commission.
- Contains more than 30 recommendations to phase out animal testing for each (eco)-toxicological endpoint.
- Describes indicators that will help to monitor the progress of implementing the actions.
- Defines organisational structures to steer its implementation and foster collaboration between the Commission, EU agencies, Member states, stakeholders, scientific experts.
- Outlines a framework for prioritising test methods for the development, validation, qualification and standardisation that will support the accelerated uptake of non-animal approaches.
- Identifies options to enhance international collaboration with global partners to drive scientific progress and accelerate international regulatory acceptance of non-animal approaches for chemical safety assessment.

The implementation of the roadmap will require joint efforts to reach the goal of phasing out animal testing in chemical safety assessments. The Commission calls on Member States, the EU agencies ECHA, EFSA and EMA, industry, academia, NGOs and all parts of society to take part in the actions listed in this roadmap. By 2029 it will organise a high-level conference to take stock of the progress made, in particular the increase of the use and uptake of non-

[78] See SWD (2026) 144 Chapter 6. 'Indicators – managing change by measuring it'.

animal approaches in all relevant EU legislation, including REACH, and seek views on the strategic way forward.

ANNEX

Table 1: Overview of the actions and how they relate to the pillars

	Actions	Timeline/Milestones/Indicators
Pillar I - Making change happen – towards phasing out animal use		
Replacing, reducing or refining animal testing in the short- to long-term		
1	The Commission will **actively support the implementation of more than 30 concrete and targeted recommendations to replace, reduce or refine animal testing** in the short to long term, including: • 16 actions for human health safety assessments across multiple domains and sectors (see Table 2), and • 16 actions covering five domains of environmental safety assessments (see Table 3). The identified actions are described in more detail in the SWD. To advance their implementation, the Commission will integrate relevant outputs from PARC or other EU research initiatives on non-animal approaches and frameworks for chemical safety assessment.	- Short-, mid- and long-term actions and milestones according to Tables 2 and 3 (continuous work from 2026 on). - The Commission will either adopt or make legislative proposals, as appropriate, to implement short-term actions in relevant Union legislation latest by the end of 2029. - Approaches covered by medium-term actions will be implemented immediately after the steps required for validation, adaptations, etc. have been finalised. - Long-term actions will be implemented after the necessary approaches have been developed and validated. - Work on all actions will start immediately as part of the roadmap's implementation. The Commission will regularly report on the implementation of short-/medium- and long-term actions via the dashboard.
2	The Commission will invite EFSA and ECHA to organise a workshop in 2026 on the implementation of roadmap actions for the pesticides and biocides area.	- Workshop on roadmap actions for the pesticides and biocides area in 2026.
Supporting the change		
3	The Commission's Joint Research Centre (JRC) will **provide access to the experimental facilities of its EU Reference Laboratory for alternatives to animal testing**. It will also	- Access to experimental facilities of EU Reference Laboratory for alternatives to

	identify research and technology infrastructure that companies can use to test, scale and validate new alternative-approach-related products, to accelerate time to market and boost commercialisation success.	animal testing EU reference laboratory for alternatives to animal testing from 2026 onwards. - Identification of research and technology infrastructure by 2027. - Indicator: number of companies or researchers using EU Reference Laboratory for alternatives to animal testing facilities.
4	The Commission will **promote the dynamic Catalogue of Transitional Initiatives** created during the roadmap's development, periodically enrich it with publicly available information and conduct analyses of initiatives to inform prioritisation efforts and foster communities of practice in regulatory science.	- Catalogue of Transitional Initiatives launched in 2024 and continuous activity. - First analysis for informing prioritisation by 2027.
Identifying regulatory needs - Supporting validation, qualification and standardisation		
5	The Commission will set up a mechanism to **identify regulatory needs** by involving EU agency collaborative structures to collect input. A report on key areas of regulatory needs for alternatives to animal testing will be published in 2027 and updated on a regular basis.	- First report on key areas of regulatory needs for alternatives to animal testing latest by end of 2027. - Update at least every three years.
6	The Commission will **provide information about options for funding** activities that support the validation, standardisation or qualification of non-animal approaches, including the following options that have already been published: - the last work programme for 2026-2027 under Horizon Europe published 11 December 2025; - the pre-commercial procurement action under the Horizon Europe chapter 'European Innovation Ecosystems'; - the European Research Area policy action announced in the life sciences strategy to fund and support the development, validation and uptake of new approach methodologies for assessing new medicinal products and medical devices. The Commission will track and report on the amount of funding provided for validation of alternative methods by Member State and Commission programmes between 2026 – 2029.	- Information on funding options provided at the latest in 2027. - Call will open on 1 June 2027. - Call opened on 10 February 2026. - Amount of funding provided in period 2026-2029 reported at the end of this mandate.

7	The Commission will **continue to encourage the preparation and updating of European standards** in the field of life sciences, in particular for *in vitro* biotechnologies such as organ-on-chip devices, induced pluripotent stem cells, 3D-tissue models, and *in vitro* measurement technologies such as high content imaging and multi-omics.	- From 2026 on and continuous activity. - Indicator: The number of (updated) standards reported via the dashboard.
8	The Commission will work to **make the validation process more effective and efficient** by: - leading with the US and the Netherlands on the revision of OECD Guidance Document 34, including the development of readiness criteria for non-animal methods and defined approaches; - working on the optimisation of both the EU Network of Laboratories for the validation of alternative methods (EU-NETVAL) and the PARERE network, together with the national contact points for Directive 2010/63/EU.	- Revision of OECD GD 34 by end of 2027. - Discussion with national contact points, EU-NETVAL and PARERE network on optimisation in 2026. - Proposals for optimising the work of the EU NETVAL and PARERE network by 2027. - Milestone: in 2029, the Commission will report on the number of non-animal test guidelines proposed by the EU for international agreement (at OECD, ICH or VICH level) since the roadmap's adoption.
Regulatory exploration spaces and safe spaces		
9	The Commission - together with the EU agencies and with the support of the European Partnership for Alternative Approaches to Animal Testing (EPAA) - will **organise a workshop on regulatory exploration spaces and the safe-space model** to capture lessons learned and identify best practices across sectors	- Workshop on safe spaces and regulatory exploration spaces in 2026. - Report on options for using safe spaces in 2027.
10	The Commission will ask EFSA, taking into account EMA's experience, to explore the possible creation of a **RES for the qualification of non-animal approaches, with nanomaterials risk assessment** as a first example of possible implementation.	- By the end of 2027.
11	The Commission will ask ECHA and its Member State Committee (MSC) to strengthen their efforts to **accept animal testing proposed by registrants only as the last resort**, in line with the objective of this roadmap.	- Request by the Commission in 2026. - The number of animal tests will be monitored as a key indicator.
Pillar II - Keeping Europe at the forefront of research and innovation on alternatives		
12	The Commission and EU agencies will **enable AI to support the roadmap** by:	- Workshop on AI-based tools latest by the end

	- accelerating the development of AI-based tools and their integration into relevant roadmap actions, including AI-powered knowledge discovery and evidence synthesis, and the development of predictive models for health and environmental effects; - ensuring that the AI-powered interactive tool under the life sciences strategy supports development of non-animal approaches for chemical safety assessment; - means of a Horizon Europe call on generative AI in biomedical research that opened on 22 May 2025, which could develop tools of use for medicines chemical safety assessment.	of 2027. - Development and integration of AI-based tools into roadmap actions: continuous activity from 2026 on. - AI -powered interactive tool under the life sciences strategy developed by 2027. - Reporting on developed AI-based tools and further development needs for phasing out animal testing by end of 2029.
13	The Commission will evaluate the European Health Data Space Regulation to **leverage human-relevant data for the development of non-animal approaches**.	- Evaluation of possibilities at the latest in 2027.
14	The Commission will **drive breakthrough innovation** dedicated to non-animal approaches through: - the European Innovation Council Advanced Innovation Challenge for which a call opened on 3 December 2025; - a Horizon Europe call on non-animal methodologies for biomedical research and regulatory testing which opened on 10 February 2026; - the launch of a matchmaking strategic interface to connect life science start-ups, industry and investors, to help fast-track alternative-approach-related start-ups reaching the market.	2026 - 2027
Pillar III - Working together in Europe and beyond		
15	The Commission will **set up a Roadmap Steering Team** immediately after the adoption of the roadmap, involving stakeholders.	- Roadmap Steering Team set up by mid-2026. - First meeting of the Roadmap Steering Team at the latest in Q3 2026.
16	The Commission will ensure that the EU agencies and Member States can effectively support implementation of the roadmap by: - setting up **collaborative structures** or by ensuring that already existing structures are fit for purpose; - asking the EU agencies to set up an **inter-agency working group on non-animal approaches** within the EU Agency Network;	- Request to EU agencies on collaborative structures in 2026. - ECHA collaborative platform set up in 2026. - Request to EU agencies on an inter-agency working group in 2026.

17	The Commission will continue to actively promote the **acceptance of non-animal approaches in international fora**. To this end, the Commission will **organise a workshop** at the latest in 2027 including with authorities from non-EU countries to launch international discussions on a new risk assessment framework based on non-animal approaches.	- Promotion in international fora: continuous activity. - Workshop at the latest in 2027. - The Commission will report regularly on international activities.
18	The Commission will create an **electronic information hub** to promote engagement with stakeholders and the general public to facilitate access to information on non-animal approaches. It will further provide **interactive materials** related to the use of animals in regulatory science.	- Electronic information hub developed and tested by end of 2027. - Interactive material prepared by end of 2027.
19	The Commission will **map existing training resources** provided by the Commission and EU agencies on non-animal approaches. It will **identify additional training needs**, taking into account its foresight study announced as part of the EU life sciences strategy.	- Mapping of training resources and needs by end of 2026. - Continuous activity to update training needs.
Monitoring progress and reporting		
20	**Immediately after the publication of the roadmap, the Commission will establish the indicators** mentioned in this table and linked action points. In addition, the Commission will **assess the need for, and develop an indicator framework** to monitor roadmap implementation, taking into account synergies with indicators under the Safe and Sustainable by Design Framework.	- Implementation of a set of indicators linked to individual actions by end of 2026. - Assessment/development of additional indicators during roadmap implementation. - Further indicators implemented by end of 2027 and continuous activity.
21	The Commission will implement the necessary tools to **obtain data on animal use for chemical safety assessments outside the EU** used for the purposes of EU legislation, by introducing changes to IUCLID[Error! Bookmark not defined.], or from the common data platform on chemicals.	- Change of IUCLID format and use of common data platform assessed by end of 2026. - First report on animal use outside of the EU at the latest in 2028.
22	The Commission will **regularly report via a public dashboard** on the implementation status of roadmap actions.	- Dashboard launched by the end of 2026. - Reporting: continuous activity.

Table 2: Opportunities for replacing, reducing or refining animal testing for human health assessments, – Pillar I – Action 1

High-level goal	**Means to achieve it**	**Specific linked actions[79]**	**Sector**	**Time frame**
Replacement	Replacing *in vivo* study with computational methods	Use of computational models for acute oral toxicity, pharmacokinetic modelling	Industrial chemicals	Short-term
	Replacing *in vivo* study with *in vitro* assays	Use of *in vitro* assays to predict/measure developmental neurotoxicity, malformations and embryofoetal lethality, pyrogenicity, sensitisation	Cross-sectoral	Short-/mid-term
Reduction	Waiving of *in vivo* tests based on historical experience	Data gathered and analysed that support waiving or deleting long-term systemic toxicity in second species	Cross-sectoral	Short-/mid-term
	Reduction through omission of certain assays	Proposal to reduce and replace animal studies for genotoxicity or carcinogenicity	Cross-sectoral	Mid-term
	Reduction/waiving of studies based on target patient population	Reduction of repeated dose toxicology (RDT) studies for advanced cancers or severely debilitating/life-threatening diseases	Pharmaceuticals (H)	Short-/mid-term
	Reduction based on additional data *in vitro*/*in silico* approaches	Reduction through use of complex *in vitro* models to predict drug-induced liver injury / pharmacokinetic parameters / cardiotoxicity / immunotoxicity	Pharmaceuticals (H)	Short-/mid-term
	Reduction based on *in silico* approaches	Reduction of control animals included in RDT testing through use of virtual control groups	Pharmaceuticals (H)	Short-/mid-term
	Reduction through study design optimisation	Several approaches (*a priori* statistical considerations, reductions of dose groups or recovery animals where possible)	Cross-sectoral	Short-/mid-term
	Reduction through incorporation of multiple readouts in one study	Reduction of *in vivo* studies through inclusion of additional endpoints in repeated dose toxicity studies, based on retrospective data/experience Waiving of long-term *in vivo* studies through shorter omics-enhanced studies	Cross-sectoral	Short-term

[79] Described in more detail in the SWD (2026) 144.

Refinement	Refinement of *in vivo* studies where not yet replaceable	Use of evident toxicity rather than lethality as endpoint in acute toxicity studies	Cross-sectoral	Short-term
Establishing an overarching, non-animal scientific assessment framework	Development of new assessment framework	Characterising protection and confidence levels of traditional assessment and non-animal-based scientific assessments based on a new scientific assessment framework	Cross-sectoral	Long-term
	Development of new assessment framework	Developing a non-animal-based classification system	Cross-sectoral [80]	Long-term
	Development of new assessment framework	Describing toxicity through changes measured at molecular level rather than adverse effects in organisms	Cross-sectoral	Long-term
	Frameworks for specific endpoints	To design (for selected endpoints below) a non-animal approach *in vitro*/*in silico* battery able to reliably distinguish between non-toxic and potentially toxic substances. To obtain a qualitative system with high sensitivity suitable for tiered hazard assessment and agree on characterising the endpoint, based on non-animal information feeding a weight-of-evidence assessment. - Genotoxicity - Carcinogenicity - Reproductive toxicity - Endocrine disruption - Nanomaterial assessment.	Cross-sectoral	Mid-term

[80] Excluding pharmaceuticals.

Table 3: Opportunities for replacing, reducing or refining animal testing for environmental safety assessments, – Pillar I – Action 1

High-level goal	Means to achieve it	Specific linked actions[79]	Time frame
Acute aquatic toxicity			
Reduction / Replacement	Adapt legislation and guidance	Reduction or replacement based on available methods (*in silico*, *in vitro*, information from taxa other than fish or more sensitive endpoints)	Short-term
Reduction	Alternative approach development	Explore waiving options based on scientific considerations while maintaining an equivalent level of protection	Short-to mid-term
Reduction / Replacement	Frameworks for specific endpoints	Develop an approach for the assessment of acute aquatic toxicity based fully on non-animal approaches	Mid-/ long-term
Bioaccumulation			
Reduction / Replacement	Adapt guidance and legislation	Reduction or replacement based on available methods (*in silico*, *in vitro*, information from other taxa than fish)	Short-term
Reduction	Alternative approach development	Explore waiving options based on scientific considerations while maintaining an equivalent level of protection	Short-to mid-term
Replacement	Frameworks for specific endpoints	Develop an approach for the assessment of bioaccumulation based fully on non-animal approaches	Mid-to long-term
Chronic fish toxicity			
Reduction	Adapt test guidelines, guidance, legislation	Clarify regulatory requirements for fish testing and waiving options (e.g. using information from taxa other than fish) based on scientific considerations while maintaining the level of protection	Short-term
Reduction / Replacement	Alternative approach development	Gain a better understanding of how to make maximal use of information from existing *in vivo* and non-animal approaches: • link different lines of evidence from non-animal approaches; • develop a reference dataset of *in vivo* chronic fish effects / endpoints, among others, for the generation of acute to chronic ratios; • develop a reference dataset relating chronic invertebrate effects to *in vivo* chronic fish effects.	Mid-term
Replacement	Frameworks for specific endpoints	Define a non-animal approach for assessing chronic fish toxicity based on *in silico* and *in vitro* methods	Long-term
Endocrine Disruption (ED) for environmental safety assessments (ESA)			
Reduction / Replacement	Adapt test guidelines,	Adapt test guidelines / guidance / legislation to maximise information from *in vivo*	Mid-term

/Refinement	guidance, legislation	testing and use tests both for concluding on the ED properties and risk assessment	
Reduction	Validation, case studies	Validation of certain *in vivo* methods (EAMA, LATT, FET[81] with thyroid endpoints)	Mid-term
Reduction / Replacement /Refinement	Research, case studies	Gain a better understanding of how to make maximum use of information from existing non-animal approaches, including those for the assessment of human health, and by linking different information from non-animal approaches[82]	Mid- / long-term
Refinement	Research, case studies	Map mechanisms and applicability domains of eleuthero-embryo methods[83]	Mid-term
Replacement	Research, case studies	Build evidence on cross-species extrapolation by exploring key events/ adverse outcome pathways (AOPs) for different species	Mid- / long-term
Replacement	Frameworks for specific endpoints	Define a framework for assessing ED for environmental safety with a mechanism-based panel of *in silico* and *in vitro* assays taking into account knowledge of (quantitative) AOPs	Long-term
Long-term change for environmental safety assessment for all taxa (including mammals and birds)			
Replacement	Development of new assessment framework	Develop non-animal environmental NGRA and implement it for environmental safety assessments	Long-term
General		It is important to explore the links between environmental safety assessments and human health NGRA approaches under a One-Health concept to ensure the best use of data	Mid- / Long-term

[81] EAMA = Extended Amphibian Metamorphosis Assay; LATT = Larval Amphibian Toxicity Test; FET = Fish Embryo Acute Toxicity Test.
[82] See SWD (2026) 144 chapter 3.4 for sub-actions.
[83] OECD TG 251; OECD TG 252; OECD TG 248.