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COMMUNICATION FROM THE COMMISSION

on the European Citizens' Initiative (ECI) 'Save cruelty-free cosmetics – Commit to a Europe without animal testing'

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1. INTRODUCTION: THE EUROPEAN CITIZENS' INITIATIVE

EU citizens can ask the European Commission to submit a proposal for legislation on a matter they consider requires legal action to uphold the EU treaties. To do so, they must submit a European citizens' initiative (ECI) under Article 11(4) of the Treaty on European Union, which requires collecting the signatures of at least one million nationals of a significant number of Member States. Regulation (EU) 2019/788[1] (the 'ECI Regulation'), which applies as of 1 January 2020, sets out detailed rules on the ECI.

'Save cruelty-free cosmetics – Commit to a Europe without animal testing' is the ninth ECI[2] to reach the thresholds required by the Treaty on European Union and the ECI Regulation. It is also the fifth successful initiative on animal welfare or the environment. The initiative calls on the Commission to take action on the use of animals for scientific purposes, as set out below.

1) *Protect and strengthen the cosmetics animal testing ban. Initiate legislative change to achieve consumer, worker, and environmental protection for all cosmetics ingredients without testing on animals for any purpose at any time.*
2) *Transform EU chemicals regulation. Ensure human health and the environment are protected by managing chemicals without the addition of new animal testing requirements.*
3) *Modernise science in the EU. Commit to a legislative proposal plotting a roadmap to phase out all animal testing in the EU before the end of the current legislative term.*

Following the organisers' request on 21 May 2021, the Commission registered the initiative[3] on 30 June 2021. On 25 January 2023, after verification of the statements of support by the Member State authorities, the organisers submitted the initiative to the Commission[4]. The Commission has examined the initiative on the basis of the ECI Regulation.

[1] Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative; OJ L 130, 17.5.2019, p. 55–81

[2] https://europa.eu/citizens-initiative/initiatives/details/2021/000006_en

[3] Commission Implementing Decision (EU) 2021/1136 of 30 June 2021 on the registration of the European citizens' initiative entitled 'Save Cruelty-free Cosmetics – Commit to a Europe without Animal Testing', pursuant to regulation (EU) 2019/788 of the European Parliament and of the Council

[4] The annex to 'Save cruelty-free cosmetics – Commit to a Europe without animal testing' ECI provides further procedural details about the initiative, including the required thresholds, and the number of statements of support.

The organisers detailed the objectives of the initiative in a meeting with the Commission on 17 March 2023[5] and at the public hearing organised by the European Parliament on 25 May 2023[6]. Furthermore, on 10 July 2023, the Parliament held a plenary debate on the ECI.

This Communication sets out the Commission's legal and political conclusions on the initiative and any action it intends to take in response to the initiative in accordance with Article 15(2) of the ECI Regulation.

2. CONTEXT

Article 13 of the Treaty on the Functioning of the European Union recognises the need to protect animals as sentient beings. It requires the EU and its Member States to pay full regard to the welfare requirements of animals in formulating and implementing the EU's agriculture, fisheries, transport, single market, research and technological development and space policies.

The EU's legislative and policy framework has been globally recognised as leading in the areas of phasing out the use of animals and promoting animal welfare. Major achievements of this policy include the introduction of the full ban on animal testing for cosmetics in the EU in 2013[7] and the more than EUR 1 billion in funding provided to research and innovation initiatives using non-animal methods across the EU f in the last two decades.

The use of animals in science constitutes a major cross-cutting issue. Notwithstanding progress made, a large number of animals are still used for testing in Europe. Animals are used for several purposes in research and safety assessment of chemicals and medicines where no alternatives are available to provide a high level of protection of human health and the environment (including animal health).

In 2020, 7.9 million animals in total were used for testing for research, training and education, or for regulatory purposes in the EU (excluding the UK) and Norway[8]. This number is 7.5% lower than in 2019 (8.5 million) and 11.4% lower than in 2018 (8.8 million)[9]. The most-used species were mice (49%) and fish (27%). As in previous years, the main purpose of animal use was research (72%), 41% of all use being for basic research and 31% for translational and applied research. Of all animal use 17% was to satisfy regulatory requirements as itemised below, followed by animals used for routine production (5%), including the production of antibodies or blood-based products. Of all animal use to satisfy regulatory requirements (1.4 million occurences in total), 54% was for human medicinal products, 22.8% for veterinary medicinal products, 8.7% for industrial chemicals (this is related to chemicals legislation such

[5] Meeting of the organisers of the 'Save cruelty-free cosmetics' European citizens' initiative with the European Commission (europa.eu); https://audiovisual.ec.europa.eu/en/reportage/P-060517

[6] ECI-Hearing 'Save cruelty-free cosmetics – Commit to a Europe without animal testing'; https://www.europarl.europa.eu/committees/en/eci-hearing-save-cruelty-free-cosmetics-/product-details/20230524ECI00141

[7] Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics (COM/2013/0135 final)

[8] https://webgate.ec.europa.eu/envdataportal/content/alures/section1_number-of-animals.html

[9] The 2020 decrease is also partially due to reduced activities from lockdowns and cancelled or postponed projects as a result of the COVID-19 pandemic.

as the REACH Regulation[10]), 2.8% for feed and food products, 4.8% for plant protection products, 3.6% for medical devices, 0.3% for biocides and 3.0% for other purposes.

2.1. Legislative acts relevant to animal testing

The body of EU law affecting animal testing is rather broad and, in principle, could be split in three categories. In the first one, there is the Directive 2010/63/EU on the protection of animals used for scientific purposes [11] that sets general goals and rules on the welfare of animals used in testing when animal use cannot be avoided. The second one consists of cross-cutting acts targeting chemicals such as the REACH Regulation, which contains cross-sectoral rules. The third one represents multiple sectoral legal acts setting out rules for the assessment of chemicals used in specific sectors or products. Both the REACH Regulation and sector-specific EU legal acts contain data requirements or provisions leading to animal testing to assess potential impacts of products and substances on human or animal health or on the environment.

2.1.1. Legislation to protect animals used for scientific purposes

The **Directive on the protection of animals used for scientific purposes** sets the ultimate goal of fully phasing out all animal use for research and for regulatory purposes in the EU. Another cornerstone of the Directive is the need to comply with the principle of the Three Rs:

- replacement of studies relying on animals by using methods not involving live animals
- reduction: adaptation of test methods or assessment approaches in a way that reduces the number of animals needed for a scientifically sound outcome
- refinement of methods that help minimise pain, suffering and distress experienced by the animals used or increase their welfare.

The Directive also lays down the specific duties of the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM)[12], which is an integral part of the Commission's Joint Research Centre (JRC). It carries out a range of activities to promote the use of non-animal methods in legislation, biomedical science and education. The Directive entrusts the EURL ECVAM with the development of alternative approaches, participating in and coordinating validation and setting up databases and information systems, among other things. The Directive requires Member States to regularly provide statistical data[13] on the use of animals for scientific purposes. It also requires the Commission to set up dedicated, publicly available databases[14].

2.1.2. Cross-cutting EU law on chemicals

[10] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC OJ L 396, 30.12.2006, p. 1–849

[11] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33.

[12] EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) (europa.eu) https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en

[13] See latest statistics report https://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm

[14] Public statistics database https://webgate.ec.europa.eu/envdataportal/content/alures/section1_number-of-animals.html

The REACH Regulation is a cross-cutting legal act on chemicals, which requires the provision of information on chemicals to ensure their safe manufacture, import and use. The Annexes to the REACH Regulation specify methods for generating hazard information, several of which are still animal test methods. However, registrants are only allowed to use animal testing as a last resort. Vertebrate animal tests should be replaced whenever possible by alternative methods. Annex XI to the REACH Regulation lists alternative methods to adapt the standard testing regime and the European Chemicals Agency (ECHA) provides comprehensive guidance[15].

Furthermore, the REACH Regulation contains specific rules on data sharing to avoid unnecessary tests. Finally, the REACH Regulation provides for prior validation of testing proposals, which ensures that animal testing is only used as a last resort and only when required.

The use of available alternative methods under the REACH Regulation is ensured by their listing in the Test Methods Regulation[16], among other things. The recent revision of this Regulation will lead to an accelerated uptake of test methods once they are adopted by the Organisation for Economic Cooperation and Development (OECD) since it now refers directly to the OECD methods instead of describing them in the regulation.

Note also that a planned targeted revision of the REACH Regulation could be an opportunity to include the generation of more hazard information e.g. on endocrine disruption for all substances and more information on substances registered in the lowest tonnage range. The exact delivery mechanism under the revised REACH Regulation is still under discussion.

2.1.3. Sectoral legislation

Cosmetics Regulation

The **Cosmetics Regulation**[13] is the most advanced EU legal act as regards phasing out animal testing since it bans the placing on the market of cosmetic products that have been tested on animals to meet the requirements of the Regulation. The animal testing ban under the Cosmetics Regulation is discussed in detail in section 3.1.

Plant Protection Products Regulation and Biocidal Products Regulation

The **Plant Protection Products Regulation**[17] and the **Biocidal Products Regulation**[18] (the 'BPR') provide that unnecessary animal testing must be avoided. Both Regulations set out the requirements for the submission of data in applications for the approval of substances under these regulations. The design of studies must take full account of the Three Rs principle, in particular when appropriate validated methods become available. Applicants must share data to avoid vertebrate studies and duplication. In particular, a mandatory data-sharing mechanism

[15] List of guidance documents on REACH is available on the ECHA's website: https://echa.europa.eu/guidance-documents/guidance-on-reach.

[16] Council 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) OJ L 142, 31.5.2008, p. 1.

[17] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1.

[18] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products OJ L 167, 27.6.2012, p. 1–123

has been set up for studies on biocidal active substances and biocidal products involving vertebrates: a prior request to ECHA to check if such studies have already been submitted under the BPR is needed before initiating studies. The information requirements laid down in Annexes II and III to the BPR were amended in 2021[19] to address new testing strategies favouring *in vitro* methods over *in vivo* testing.

Medicinal products for human use

The general legal framework on **human medicines** consists of Directive 2001/83/EC[20] and Regulation (EC) No 726/2004[21]. It fully takes into account the Three Rs principle as introduced by Directive 2010/63/EU. The regulatory authorities in the EU will accept all validated methodologies supporting this principle. Alternative testing approaches that have not been assessed in a formal validation process can also be accepted by the responsible authorities (i.e. European Medicines Agency and national competent authorities) on a case-by-case basis and following an evaluation of the data submitted by the applicant.

Furthermore, abridged marketing authorisation applications (e.g. for generics and biosimilars) and informed consent applications can rely on the preclinical and clinical studies conducted for the purpose of obtaining a marketing authorisation of a reference medicinal product. In such cases, the applicant refers to the data that was submitted by the originator (there is no duplication of tests).

The above mentioned EU general pharmaceutical legislation for human medicinal products has been reviewed recently and the Commission adopted a new legal proposal[22] on 26 April 2023. Some proposed changes aim to strengthen the Three Rs principle across the lifecycle of a medicinal product. In addition, the legislative proposal strengthens the current rules by adding obligations for marketing authorisation applicants or holders and by facilitating alternative testing approaches. The new rules will also encourage more cooperation between EU agencies and the national competent authorities in assessing substances, facilitating data sharing and carrying out joint non-clinical studies to avoid unnecessary duplication of tests with live animals. The proposal also aims to future-proof the legislation in order to allow the use of alternative testing methods.

Veterinary medicinal products

The EU legal framework on **veterinary medicines** was revised by Regulation (EU) 2019/6[23]. It requires applicants for authorisation of any veterinary medicinal product to use the minimum number of animals in the control tests carried out during the manufacturing process of both

[19] Commission Delegated Regulation (EU) 2021/525 of 19 October 2020 amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products. OJ L 106, 26.3.2021, p. 3–28

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ L 311, 28.11.2001, p. 67.

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.

[22] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency. COM/2023/193

[23] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p. 43.

immunological and non-immunological veterinary medicinal products, and on finished immunological veterinary medicinal products. Alternative *in vitro* test must be used when this leads to replacement or reduction of animal use or reduction of suffering. As for human medicines, some marketing authorisation applications (e.g. for generics) can rely on the studies in animals conducted for the reference veterinary medicinal product. Regulation (EU) 2019/6 also provides the possibility of granting other prospective applicants access to data via a letter of access (e.g. for applications based on informed consent) to avoid unnecessary animal testing.

Clinical trials for veterinary medicinal products are exempted from the scope of Directive 2010/63/EU on the protection of animals used for scientific purposes since the legislation on veterinary medicinal products already provides appropriate animal-welfare measures: clinical trials should take into account the Three Rs principle, use alternative test methods wherever possible and take into account the guidelines of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products[24].

Medical devices

The legal framework on **medical devices** was revised in 2017 with the adoption of the Regulation on medical devices[25] and the Regulation on in-vitro diagnostic medical devices[26]. In few cases tests on animals may take place, for pre-clinical studies. These tests must be conducted in accordance with Directive 2010/63/EU.

2.2. Current EU policy context

On 14 October 2020, the Commission adopted its Communication on C*hemicals Strategy for Sustainability – Towards a Toxic-Free Environment* under the European Green Deal[27]. This Strategy has a dual goal: improving protection of people's health and the environment and boosting innovation for safe and sustainable chemicals. The Strategy announces the revision of the EU's framework of chemical legislation and reiterates the EU's ultimate goal of full replacement of animal testing, committing to fostering multidisciplinary research and digital innovations for advanced tools, methods and models, and data analysis capacities.

The strategy lists 85 action points, of which several support reducing or phasing out animal testing. For instance, the proposal for a regulation on chemicals data[28] under the 'one substance, one assessment' umbrella would bring available information on chemicals together on one platform. This could help authorities group chemicals for risk management or support read-across, reducing the need for animal data. Another example is the Commission Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials[29], which promotes the use of new approach methodologies

[24] https://vichsec.org/en/home.html

[25] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, OJ L 117, 5.5.2017, p. 1-175

[26] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[27] COM/2019/640. https://commission.europa.eu/document/daef3e5c-a456-4fbb-a067-8f1cbe8d9c78_en

[28] Chemical safety – better access to chemicals data for safety assessments (europa.eu)

[29] Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials

(NAMs) for chemical safety assessment, integrating them into the design and development of chemicals as early as possible.

In September 2021, the Parliament adopted a resolution[30] requesting to accelerate the transition to innovation without the use of animals in research, regulatory testing and education. The Commission responded to the resolution measures by outlining the actions it takes to reduce animal testing[30].

2.3. EU research on alternative approaches, education and training

During the last two decades, the Commission has invested more than EUR 1 billion into over 300 research projects related to alternative methods to animal testing. Many of these projects have generated new tools and methods that are used for regulatory purposes, to predict the safety of chemicals, to understand diseases, or to assess the effectiveness of new treatments.

The EU Framework Programmes for Research and Innovation, Horizon 2020 and Horizon Europe, fund ambitious research projects on alternatives to animal testing. Two prominent examples are the ASPIS cluster on animal-free safety assessment of chemicals with a budget of EUR 60 million from Horizon 2020[31] and the PARC partnership with a total budget of EUR 400 million, of which EUR 200 million is provided by Horizon Europe[32,33]. ASPIS provides NAMs to improve the accuracy, speed and affordability of chemical safety testing without using laboratory animals. It is currently developing a framework, called the ASPIS Safety Profiling Algorithm (ASPA), based on a tiered approach for Next Generation Risk Assessment (NGRA) in the safety assessment of chronic adverse health effects associated with chemical exposure. PARC aims to support the move towards NGRA and the increased acceptance and use of NAMs. Against this background, a good collaboration between ASPIS and PARC is set up in this context. PARC is also supporting the development of a toolbox for implementing the 'safe and sustainable by design' framework promoting the use of *in silico* tools in risk assessment.

The 2023-2024 work programme of Horizon Europe Cluster 1 "Health" will complem these important initiatives by funding research project on alternatives to animal testing in biomedical sciences in areas with limited translational value of animal-based approaches, the highest use of animals, or the most severe animal suffering (EUR 25 million; submission deadline 19 September 2023). To foster uptake of alternatives to animal testing, the 2023-2024 Work Programme of Horizon Europe cluster 1 contains a topic aiming to support the training of regulators and improve regulatory uptake (topic submission deadline 11 April 2024)[34].

The Innovative Medicines Initiative Joint Undertaking, the predecessor of the Innovative Health Initiative Joint Undertaking, also invested in alternatives to animal methods. These projects have generated, among other things, an *in silico* test to predict the toxicity of chemicals,

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[30] Procedure File: 2021/2784(RSP) | Legislative Observatory | European Parliament (europa.eu)

[31] Animal-free Safety assessment of chemicals: Project cluster for Implementation of novel Strategies. (aspis-cluster.eu)

[32] Partnership for the Assessment of Risks from Chemicals | Parc (eu-parc.eu)

[33] Marx-Stoelting, P., Rivière, G., Luijten, M. *et al.* A walk in the PARC: developing and implementing 21st century chemical risk assessment in Europe. *Arch Toxicol* **97**, 893–908 (2023). https://doi.org/10.1007/s00204-022-03435-7

[34] European Commission Decision C(2023) 2178. Horizon Europe Work Programme 2023-2024. 4. Health. 31 March 2023

and accelerate drug development without using animals. The Innovative Health Initiative Joint Undertaking[35] will continue investing in the development of alternatives to animal testing and fostering uptake by the health industry. A relevant topic is planned to be launched before the end of 2023.

Awareness, education and training are essential to foster the use of non-animal methods, as highlighted also by the ECI. While education and training formally are a Member State responsibility, the EURL ECVAM is engaged in several education and training activities aiming at increasing the awareness of Three Rs principle at the levels of secondary school, university and early professional training. The core business of this activity is the deployment of a proper strategy to produce a comprehensive set of teaching resources, and a set of guidance documents to inform educators and educational institutions about effective ways of creating, adapting and implementing curricula and practices specific to the teaching of Three Rs principle. Furthermore, the biannual edition of the JRC Summer School on non-animal approaches in science provides students with the opportunity to learn from experts in the fields of cutting-edge technologies and computational modelling, share knowledge and experience and build professional networks. In addition, several EU projects funded under various programmes[36] supported the training of hundreds of young scientists in non-animal methods. For example, ASPIS is currently setting up an academy of young scientists on animal-free safety assessment of chemicals. The Commission, with financial support from the Parliament, developed a series of e-learning modules on various aspects of Directive 2010/63/EU, including one on how to search for existing non-animal alternatives and one on how to develop alternative methods for regulatory purposes.

2.4. International activities

The Commission is committed to developing common standards and innovative risk assessment tools internationally (notably in the OECD), and to promoting their use within international frameworks, to shift further away from animal testing, among other objectives. The Commission is actively supporting the development of OECD technical guidelines, also aiming to ensure mutual acceptance of data among OECD and other relevant countries.

Furthermore, the Commission is actively promoting the inclusion of alternative methods, including *in vitro* methods in the Globally Harmonised System of Classification and Labelling of Chemicals, helping to align international approaches and thus to create a level playing field.

2.5. Agencies, Commission scientific committees and stakeholders

The Commission relies on a wide network of expert groups, committees and in-house think tanks that provide a wealth of expertise on NAMs that will facilitate their acceptance. The Commission is in the fortunate position to receive advice on world-leading science from the JRC, including the EURL ECVAM. This knowledge is strengthened in the various regulatory

[35] https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/innovative-health-initiative-joint-undertaking-ihi-ju_en

[36] E.g. under Horizon 2020 Societal Challenge 1, Horizon Europe Health Cluster, the Innovative Medicines Initiative and the Innovative Health Initiative, Marie Curie networks, etc

areas by the agencies and the Commission scientific committees[37]. Further structures exist for example the European Partnership for Alternative Approaches to Animal Testing.

The 2023-2026 work programme of **ECHA** lists several of its planned activities of the Agency related to NAMs, e.g.:

- building internal capacity on NAMs by organising training for ECHA scientists and its committees to increase the level of knowledge on NAMs suitable for regulatory needs;
- becoming more closely involved in scientific projects addressing key aspects for regulatory acceptance[38];
- continuously developing computational tools that provide information on hazard properties[39];
- making data sets available for the development of NAMs and joint projects with EFSA on data interoperability and tools integration;
- increasing cooperation across legislations and jurisdictions within Europe and outside Europe (US Environmental Protection Agency, Health Canada) through platforms such as the European Partnership on Alternative Approaches to Animal Testing (EPAA) and Accelerating the Pace of Chemical Risk Assessment (APCRA); and
- organising sessions on non-animal methods at key conferences[40].

The European Medicines Agency (EMA) supports the ethical use of animals in the testing of human and veterinary medicinal products across the EU by promoting regulatory acceptance of testing approaches applying the Three Rs principle. It has issued specific guidance in this respect, including:

- recommendations on methods applying the Three Rs principle in the European pharmacopoeia to help marketing authorisation holders comply with new or revised measures;
- a scientific review of batch release tests for human and veterinary vaccines and biologicals to ensure that these are aligned with best practice in Three Rs; and
- a contribution to the development of harmonised guidance and requirements in Europe and globally, by working closely with relevant European and international bodies.

Furthermore, EMA has recently reactivated its dedicated 3Rs Working Party (3RsWP). The 3RsWP provides advice to the EMA's scientific committees on the use of animals in regulatory testing of medicines and the application of the Three Rs principle. The 3RsWP has set some very ambitious goals[41] for – among others – the promotion of regulatory acceptance of innovative NAMs. EMA also has an Innovation Task Force, which is a multidisciplinary group that provides a forum for early dialogue with applicants on innovative aspects in medicines development and also covers the regulatory acceptance of non-animal methods.

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[37] E.g. the Scientific Committee for Consumer Safety (SCCS), the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) or the EURL ECVAM Scientific Advisory Committee

[38] E.g Accelerating the Pace of Chemical Risk Assessment (APCRA), EU ToxRisk, ASPIS, PARC and MATCHING projects.)

[39] E.g. the OECD QSAR Toolbox or the QSAR Assessment Framework work at OECD

[40] E.g. SETAC Annual Meetings, EUROTOX, QSAR 2023

[41] Consolidated 3-year work plan for the Non-clinical domain including the priorities for 2023 (europa.eu)

The European Food Safety Agency (EFSA) is considering the development and use of non-animal methods in risk assessment as a critical step for moving towards a new paradigm based on the mechanistic understanding of toxicity and moving away from the use of animals. EFSA has sponsored several projects in various areas such as developmental neurotoxicity, chronic neurotoxicity, development of adverse outcome pathways, NAMs for nanoforms and absorption, distribution, metabolism and excretion. Furthermore, EFSA has published a NAM roadmap[42] with proposals for the development of non-animal methods and new concepts for human risk assessment relevant for regulatory purposes.

The EU's Scientific Committee on Consumer Safety (SCCS)[43] plays an important role in taking up the legislator's decision to ban animal tests under the Cosmetics Regulation. The SCCS has been closely following progress in developing and validating alternative methods. The latest revision of the *Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation* by the SCCS was published in March 2021.

Besides validated alternatives, the SCCS may also accept, on a case-by-case basis, methods that the Committee considers scientifically valid for the safety evaluation of cosmetic substances even if they have not gone through a validation process.

The **EPAA** was set up by the Commission in 2005. The EPAA brings together all Commission services with activities related to (non-)animal testing for scientific purposes, EU agencies, as well as representatives of the industry covered by the regulatory framework on chemicals and pharmaceuticals, with other stakeholders like animal-welfare NGOs, the Parliament and academic experts. The EPAA's activities include the Project Platform, where EPAA partners and associates collaborate on projects that support the development, validation, acceptance and implementation of alternatives that apply the Three Rs principle in regulatory testing and decision-making. Furthermore, the EPAA organises an annual conference on activities on these topics. The next annual conference will take place in November 2023 and aims to address the impact of the chemical strategy for sustainability and the pharmaceutical strategy for Europe on innovation and animal testing. The Partners' Forum gives EPAA members an opportunity to exchange information across sectors and to identify synergies. In addition, it provides grants and awards for outstanding contributions to the development and implementation of alternatives to animal testing, such as the EPAA Refinement Prize, which supports students and young scientists who have done outstanding work in the field of alternative approaches.

2.6. Progress following the ECI 'Stop Vivisection' of 2015

In 2015, the ECI 'Stop Vivisection' asked the Commission to put forward a new proposal aimed at phasing out the practice of animal experimentation. The Commission responded with a number of actions, which have been followed through:

1. **Accelerating progress in the Three Rs through knowledge sharing:** The ETPLAS[44] platform was created to allow a more systematic sharing of knowledge on the

[42] Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment EFSA Journal 2022;19(6):EN-7341

[43] The Committee provides Opinions on health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products) and services (e.g. tattooing, artificial sun tanning).

[44] https://learn.etplas.eu/ Education and Training Platform for Laboratory Animal Science

application of Three Rs. Six open access training e-modules are currently accessible via the platform, while thirteen additional modules will be finalised by end of 2024.

2. **Development, validation and implementation of new alternative approaches:** The Commission followed up to its commitment to support the development, validation and implementation of alternative approaches for regulatory and research use by continuing the funding of alternative approaches and with activities of EURL ECVAM on method validation. Collaborations like EPAA and APCRA support the Commission's efforts.
3. **Monitoring compliance with Directive 2010/63/EU:** The Commission and its agencies continued promoting the use of alternative approaches, e.g. for pyrogenicity testing of vaccines and biologicals[45]. The Commission also updated the Test Method Regulation to foster the use of internationally accepted alternative methods.
4. **Engaging in a dialogue with the scientific community:** The Commission committed to organise a conference engaging the scientific community and stakeholders in a debate on how to advance towards the goal of phasing out animal testing. The Commission organised two conferences on this topic in 2016 and in 2021[46].

3. EVALUATION OF THE PROPOSALS IN THE INITIATIVE AND RESPONSES

The Commission has carefully analysed the three main objectives of the ECI.

3.1. Objective 1: Protect and strengthen the cosmetics animal testing ban

Objective 1 is described in the ECI as 'Protect and strengthen the cosmetics animal testing ban. Initiate legislative change to achieve consumer, worker, and environmental protection for all cosmetics ingredients without testing on animals for any purpose at any time'. In the annex to the initiative, this objective is broken down into the below four points.

1. Immediately implement the existing EU bans on animal testing for cosmetics and the marketing of ingredients tested on animals.
2. Clarify that the assessment of cosmetics ingredients must rely on non-animal data and that animal data must be rejected, regardless of the location and purpose of animal tests.
3. Change legislation to ensure a chemical safety assessment of cosmetic ingredients, including for workers' health and the environment, without animal testing.
4. Devise a robust assessment strategy for cosmetics ingredients based on non-animal methods.

Response to objective 1:

The Commission responds to the ECI as set out below.

- The Commission emphasises that the animal testing ban for cosmetics ingredients and the marketing ban for cosmetic products containing ingredients tested on animals has been fully implemented under the Cosmetics Regulation.
- Already now, animal testing is banned for the assessment of cosmetics ingredients

[45] Joint EDQM-EPAA Event: The future of pyrogenicity testing: phasing out the rabbit pyrogen test - European Directorate for the Quality of Medicines & HealthCare

[46] Non-animal approaches - Publications Office of the EU (europa.eu) (2017); Towards replacement of animals for scientific purposes - Publications Office of the EU (europa.eu) (2021)

under the Cosmetics Regulation.

- The Commission does currently not intend to propose legislative changes to the Cosmetics Regulation nor to the REACH Regulation as regards the testing of cosmetics ingredients. The interface between the two Regulations is currently under scrutiny by the General Court in two cases brought against ECHA. The Commission will analyse the judgments, once available, and take them into account when deciding on the need for legislative changes.
- Furthermore, as part of the targeted revision of the REACH Regulation, the Commission intends to propose replacing some information requirements based on animal testing with non-animal methods, where possible.
- The request for a robust assessment strategy for cosmetics ingredients based on non-animal methods appears to be similar to the requests made under objective 2 of the ECI for steps to develop and implement non-animal approaches to chemical safety assessments and for an aligned transition in the regulatory space to non-animal approaches. Therefore, the request is replied to in section 3.2.

Already now, the Cosmetics Regulation bans the placing on the market of cosmetic products that have been tested on animals to meet the requirements of this Regulation. The ban, which has been fully applicable since March 2013, also concerns cosmetics ingredients tested on animals for the purpose of that Regulation. Data generated through animal testing performed to meet cosmetics requirements of non-EU countries cannot be relied on in the EU for the assessment of cosmetics.

However, most ingredients used in cosmetic products are also used in other consumer and industrial products. Animal testing may be necessary to ensure compliance with rules that apply to these products. In such cases, the Commission clarified[47] that animal testing that has been motivated by compliance with non-cosmetics-related rules should not trigger the marketing ban for cosmetics. Such data can be relied on for the cosmetics safety assessment under the Cosmetics Regulation if they are relevant for this assessment[48].

Chemical substances used as cosmetics ingredients are also subject to requirements under the REACH Regulation, if produced at 1 tonne or more per year, for assessing hazards and risks to human health and the environment. In October 2014, the Commission, in cooperation with ECHA, clarified[49] the relationship between the marketing ban and the information requirements under the REACH Regulation. For chemicals that are not solely used in cosmetics, animal testing is permitted, as described above, to fulfil the requirements under the REACH Regulation.

[47] Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics, 11.3.2013, COM(2013)135

[48] Article 10 (3) of Regulation 1223/2009/EC

[49] Interface between REACH and Cosmetics regulations, Factsheet, ECHA-14-FS-04-EN; https://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf/2fbcf6bf-cc78-4a2c-83fa-43ca87cfb314

The Cosmetics Regulation requires an assessment of the risks to consumers and to professionals[50]. For these assessments, animal testing is prohibited. The REACH Regulation, however, additionally requires an assessment of the risks to workers exposed to the substance and the risks to the environment. Therefore, registrants of chemicals exclusively used in cosmetics may need to perform animal testing to satisfy the requirement to assess the risks to workers and the environment under the REACH Regulation. However, as is the case for all substances registered under the REACH Regulation, registrants must provide the required information, wherever possible, by using alternatives to animal testing (e.g., computer modelling, read-across, weight of evidence). Animal testing remains the last resort, and can, and in fact frequently is waived in accordance with the REACH Regulation.

The ECI asks for legislative changes and to expand the scope of the Cosmetics Regulation to cover the assessment of the risks to workers' health and the environment. This would require fundamental changes to this Regulation and to the REACH Regulation. This would also be the case if changes were to be made to the REACH Regulation only, i.e. a ban on animal testing for cosmetics ingredients were to be introduced under the REACH Regulation only. Changes to any of the two Regulations would lead to information gaps on risks to workers and the environment since, as indicated above, it is not yet considered sufficient to perform safety assessments for human health and the environment without any animal testing due to the lack of accepted alternative methods. It could also lead to cosmetic ingredients that are in principle safe being removed from the market because it is impossible to fully demonstrate their safety. In summary, any legislative changes would require progress in developing animal-free assessment methods and suitable criteria for their uptake and an in-depth analysis of the impacts.

The above interpretation of the interface between the Cosmetics Regulation and the REACH Regulation is currently under scrutiny by the General Court in two cases brought against ECHA. A registrant challenges the obligation to perform animal testing, requested by ECHA in dossier evaluation decisions under the REACH Regulation. The judgments are expected in the course of 2023 and may have consequences for the current interpretation underlying the Commission's response to this ECI.

Case T-655/20 and Case T-656/20 (Symrise v ECHA)

The applicants apply for annulment of two decisions of the Board of Appeal of ECHA. In these decisions, the Board of Appeal had confirmed the ECHA's request for certain tests involving animal testing for chemicals that are solely used in cosmetics.

Among other pleas, the applicant, supported by NGOs and companies active in the production of cosmetics, claims that by requesting tests on vertebrate animals for the assessment of the risks to workers' health, and by failing to take account of the safety of the substance as assessed under the Cosmetics Regulation into account, ECHA committed a manifest error of assessment and misinterpreted the REACH Regulation.

3.2. Objective 2: Transform EU chemicals legislation

[50] Professionals are understood as persons using cosmetic products as part of their business (e.g. hairdressers), while workers manufacture the ingredients or the products on an industrial site.

The ECI calls on the Commission to transform EU chemicals legislation and to ensure that human health and the environment are protected by managing chemicals without adding of new animal testing requirements. The initiative requests under objective 2 to put in place concrete steps to develop, validate, and implement human-relevant, non-animal approaches for the identification of toxic chemicals. It asks to commit to a full transition away from animal testing, ensure an uptake of non-animal methods that is aligned between all relevant regulatory agencies with administrative responsibility for chemicals, biocides, plant protection products, pharmaceuticals, and other products and to adapt regulatory frameworks to ensure a rapid uptake of NAMs. It further requests to ensure that test requirement deadlines are not applied at the expense of scientific rigour or human and environmental safety by allowing a default fallback to reliance on unreliable tests on animals. In essence, the objectives of the initiative correspond to putting in place a strategy or roadmap for a transition away from animal testing. Points mentioned under objective 2, which have been further detailed in a meeting with the Commission on 17 March 2023, appear to partly overlap with those under objective 3 asking to 'plot a roadmap' and further to prioritise the funding for developing and validating non-animal methods, also for regulatory purposes, and to coordinate the uptake of the methods. In particular, the request for concrete steps in objective 2 corresponds to setting up a roadmap towards phasing out animal testing for chemical safety assessments.

Response to Objective 2:

A roadmap towards ultimately phasing out animal testing for chemical safety assessments

The Commission will immediately launch the work to develop a roadmap that will outline milestones and specific actions, to be implemented in the short to longer term, to reduce animal testing and that would be pre-requisites for a transition towards an animal-free regulatory system under relevant pieces of chemical legislation (e.g. REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines). Core of the roadmap will be to analyse and to describe the necessary steps to replace animal testing in pieces of legislation that currently require animal testing for chemical safety assessments. The roadmap will outline the path to expand and accelerate the development, validation and implementation of non-animal methods as well as means to facilitate their uptake across legislations. The Commission intends to discuss with Member States and stakeholders elements of the roadmap at a workshop in the second half of 2023 and to present the progress made at a second workshop in the second half of 2024. It is intended to finalise the work on the roadmap in the first quarter of the term of the next Commission.

When drawing up the roadmap, the Commission will work closely with its agencies, the Member States and relevant stakeholders from NGOs, industry and research. The roadmap's development will be supported by assessments that were carried out by the Joint Research Centre, EFSA's work on non-animal approaches, the EFSA roadmap and the expertise of ECHA, EFSA and EMA.

The roadmap will include and build on the below **elements** to support the transition towards chemical safety assessments based on non-animal testing.

1. **Replacing animal testing**: While substantial progress has been made during the recent years to develop alternative methods to animal testing, it is still not possible to replace animal testing for chemical safety assessments for all (eco-)toxicological endpoints. For some endpoints, further research is necessary. For other endpoints, non-animal testing is currently not satisfying fully the regulatory needs, e.g. as regards the quantitative assessments of hazards and risks. It is therefore necessary to analyse for each (eco-)toxicological endpoint the options to replace animal testing, identify gaps that have to be closed and development needs. Furthermore, in some cases, it might be necessary to define data requirements in legislation differently so that non-animal methods can be used to fulfil regulatory needs. This analysis will be a core element of the roadmap, which will also include action points and milestones to achieve the ultimate goal of phasing out animal testing for the different endpoints.
2. **Joining forces - stakeholder involvement**: Involving stakeholders is crucial for pooling the scientific knowledge that forms the basis of the roadmap and essential to receive support from Member States, agencies and stakeholders from industry, NGOs and research. As a first step, from 31 May to 1 June 2023[51], the Commission, together with ECHA and several stakeholders, organised a workshop that took stock of the scientific developments on non-animal testing, and discussed requirements such testing need to fulfil in a regulatory context. Organisers of the ECI participated at the workshop. Participants of the workshop voiced support for developing a roadmap. towards phasing out animal testing. Continuous stakeholder involvement will be guaranteed with, among other things, a set of further workshops:
    - the Commission will organise **a workshop in the second half of 2023** to discuss the steps necessary to replace animal testing for each toxicological endpoint and the elements of a roadmap;
    - the Commission intends to organise a **second workshop** in the second half of 2024 to present the progress made on developing a roadmap as well as to receive input from Member States and stakeholders; and
    - further workshops focusing on scientific and regulatory aspects will be organised in collaboration with the EPAA or by the agencies.
3. **Strengthen collaboration of agencies and expert committees**: The Commission is currently preparing a proposal for adoption in 2023 entitled 'Streamlining EU scientific and technical work on chemicals through the EU agencies' that has the purpose to enhance the collaboration of the agencies and to increase their efficiency by making full use of synergies in the assessment of chemicals. Furthermore, the Commission will, as part of the roadmap, analyse the strengths and weaknesses of the current landscape of agencies, committees and working groups that provide advice on non-animal methods. Such action, which will be finished together with the roadmap, could also explore opportunities for a stronger collaboration and analyse possibilities to accelerate the transfer of available scientific expertise to legislation.
4. **Advisory scientific committee on non-animal methods:** As part of the work under under the roadmap, the Commission will analyse the need and feasibility of an expert scientific committee to provide advice on the development of non-animal approaches and their uptake and use in the regulatory context. The analysis will be presented together with the roadmap.
5. **Acceptance of methods**: The Commission will analyse, as part of the roadmap, ways to

[51] https://echa.europa.eu/-/echa-s-workshop-opens-way-for-animal-testing-free-chemicals-regulation

accelerate the acceptance of new non-animal methods, while taking into account the importance of mutual acceptance of data across different jurisdictions. This includes the need to increase validation but also the regulatory uptake of non-animal methods.

6. **International dimension**: The roadmap will outline ways to improve outreach activities with non -EU partner countries and multilateral organisations to foster the development and acceptance of non-animal testing methods for regulatory purposes, such as the underlying classification methods for substances and mixtures under the UN Globally Harmonised System of Classification and Labelling of Chemicals.
7. **Agencies involvement in international forums**: The EU agencies, such as EFSA, ECHA or EMA, have outstanding expertise in non-animal methods. The roadmap will analyse, in close collaboration with the agencies, possibilities to increase the agencies' visibility and impact in international forums, such as OECD at the regional and the WHO at the international level. The collaboration of regulators from the US, Canada, Europe and others in the APCRA (Accelerating the Pace of Chemical Risk Assessment) project is facilitating alignment in international forums. This work is critical to enable progress towards phasing out animal testing in the international context, i.e. in light of globally harmonised classifications and mutual acceptance of data.
8. **Improve availability and accessibility of information**: Access to information on NAMs, available knowledge bases and tools is key to accelerating the uptake of non-animal approaches. The Commission will propose in 2023 a Regulation on chemicals data that will improve accessibility to information on chemicals. Furthermore, the Commission will analyse by end of 2024, how to facilitate access to information such as upcoming events, calls, but also to guidance, e.g. through dedicated platforms and interactive communication tools. Increased availability and accessibility of information on non-animal methods will benefit industry and authorities when replacing animal testing, inform the general public and support the scientific community when developing new methods.
9. **Outreach to scientific community and stakeholders**: An exchange with all stakeholders, including the scientific community, is vital for accelerating the replacement of animal testing and for gaining support for basing chemical assessments on non-animal methods. The Commission will therefore increase its outreach to stakeholders and the scientific community, with support of its agencies, to receive the necessary input on how to replace animal testing with non-animal approaches, e.g. via the organisation of workshops (point 2), the annual conference under the umbrella of EPAA (section 2.5) or contributions to conferences.

Furthermore, as part of the revision of the REACH Regulation, the Commission intends to assess all possibilities to replace information requirements based on animal testing with non-animal methods. New animal-based information requirements would be introduced only as a last resort.

3.3. Objective 3: Modernise science in the EU – Commit to a legislative proposal plotting a roadmap to phase out all animal testing

The ECI asks to modernise science in the EU by ultimately phasing out all animal testing including for research and educational purposes. The initiative proposes reaching this goal through a ‘legislative proposal plotting a roadmap to phase out all animal testing in the EU before the end of the current legislative term’. Such a proposal should include targets regarding ‘reduction in numbers of animals used, investments in advanced non-animal models and

infrastructures, education and training synergy, and regulatory acceptance of non-animal methods. The description under the initiative's objective 3 appears to overlap with objective 2. The initiative also requests to endorse the desirability of phasing out animal testing in science.

Response to Objective 3:

The Commission responds to the ECI as set out below.

- The Commission is proposing a set of action points to accelerate the reduction of animal testing in research, education and training, including activities that will increase cooperation with Member States.
- Furthermore, the Commission will continue to support research on alternatives to animal testing with substantial funding.

The Commission reiterates that it shares the goal of phasing out animal testing, as soon as it is scientifically possible, as also mentioned in recital 10 of Directive 2010/63/EU, however it does not consider that a legislative proposal is the right way forward towards phasing out all animal testing. Directive 2010/63/EU lays down measures to protect animals used for scientific or educational purposes. It does not provide a legal framework to set up research programmes or to set reduction targets for the number of animals used, or to stimulate investments in advanced non-animal models and infrastructures, education and training synergies or the regulatory acceptance of non-animal methods. Advances in the mentioned areas can rather be reached by building and extending on existing programmes and developing specific actions as suggested below. In addition, progress in science via research programmes requires strong support from Member States. This is even more evident for actions in education and training, an area for which the Member States are responsible. Similarly, the uptake of validated methods can only be achieved with their involvement.

Setting reduction targets appears to be useful in policy areas where the possibilities to implement a policy goal can be clearly mapped out. However, this is not the case in research, where scientific progress and innovation are unpredictable, and rely on the best available methods, technologies and knowledge. In addition, setting a universal reduction target may not account for the diversity of research needs. Considerable advances have been made in developing alternatives, but animal models remain unavoidable at the moment to understand some more complex biological or physiological processes involved in health, disease and biodiversity. The Commission reiterates that at this stage, it is not possible to predict when scientifically valid methods able to replace particular animal procedures in research will become available. Consequently, setting reduction goals seems unrealistic and these would need to be constantly adjusted.

As mentioned above in section 3.2 (point 5), as a response to the requests of the initiative under objective 2, the Commission will propose to draw up a roadmap that includes the development and validation of non-animal methods for regulatory purposes as well as their uptake and acceptance in regulatory procedures for chemicals safety assessment as soon as they are available. As regards research funding, the EU is already making considerable investments in advancing non-animal approaches. This has been briefly described in section 2.3. The Commission intends to keep up the pace of funding alternatives to animal approaches.

Finally, the Commission will complement its commitments to the roadmap for chemicals safety assessment described in section 3.2 with the below specific action points to accelerate the reduction of animals used in research, education and regulatory acceptance.

1. **Further improving coordination with Member States:** The Commission is exploring the possibility of developing a **European Research Area (ERA)** policy action to **reduce animal uses in research and regulatory testing**. The involvement of a critical mass of Member States is crucial to accelerate the uptake of alternative methods and commit to a **reduction** of animal testing. This action would be a direct and potentially impactful answer to the request of the initiative to phase out animal testing in research. It could mobilise Member States, under the Commission's leadership to streamline their national and regional policies to **reduce** animal testing, while accelerating the development, validation and uptake of alternative methods. This ERA policy action would also inform all relevant stakeholders of the applicability of non-animal methods, as they become available. The Commission presented this proposal to the Member States on 25 May 2023. Member States are currently assessing their interest in participating in such action.
2. **Continued EU funding to alternatives and visibility:** The Commission already provides substantial support to research on alternatives to animal testing and will continue to do so. As mentioned in section 2.3, the 2023-2024 work programme of Horizon Europe Work Programmes 2023-2024 and the Innovative Health Initiative cover several relevant topics. The Commission also intends to include alternatives to animal testing in the next Horizon Europe strategic planning 2025-2027.
3. **Exploratory workshop(s):** The Commission intends to organise one or more workshops with experts to determine future priority areas of research. The workshop(s) will be held before mid 2025 and might be part of the workshops announced in section 3.2.
4. **Education, training and awareness:** As indicated in section 2.3, an academy of young scientists in alternatives to animal testing was set up recently under the Horizon 2020 ASPIS cluster. The Commission is exploring ways to continue this initiative.

4. CONCLUSION AND OUTLOOK

The ECI 'Save cruelty-free cosmetics – Commit to a Europe without animal testing' echoes the public concerns about the use of animals for scientific purposes, including for chemical safety assessments under various pieces of legislation.

The Commission shares the view that all animal testing for regulatory purposes should be phased out. However, this is a long-term goal that will only be reached step by step and that requires further scientific developments in identifying hazards and risks solely based on non-animal methods. In the short and medium term, animal testing remains important for assessing risks of chemicals to human health and the environment. Where possible, current revisions of several pieces of chemical legislation foster the use of non-animal approaches. For instance, the Commission intends to replace some animal-based methods currently required under the REACH Regulation and to introduce non-animal methods.

Reducing animal testing in the short and medium term and phasing out such tests in the long term will require concerted and aligned action by the Commission and its agencies, Member States, the research community and stakeholders. It further demands a clear view on the steps needed to phase out animal testing. The Commission will therefore immediately start with its

work to develop a roadmap that will outline milestones and specific actions, to be implemented from the short to longer term, to reduce animal testing with the aim to transition towards an animal-free regulatory system under all relevant pieces of chemical legislation. This roadmap will analyse necessary changes in regulatory approaches and to give the right impetus for the development, validation and implementation of non-animal methods and their rapid uptake in regulatory procedures for chemicals safety assessment. Once defined, this roadmap could serve as a model for other policy areas. The main Commission actions that will feed into this roadmap consist of a set of legsislative and non-legislative actions (outlined in detail in section 3.2):

- A step-by-step analysis of each (eco-)toxicological endpoints with the aim to define necessary actions and milestones to phase out animal testing;
- A full involvement of stakeholders in workshops in 2023 and 2024 that will discuss the roadmap. ;
- Strengthened collaboration of agencies and expert committees, among others through the adoption of the Commission proposal for adoption in the second half of 2023 entitled 'Streamlining EU scientific and technical work on chemicals through the EU agencies';
- Improving accessibility to information on NAMs, by, among others, a Commission proposal in the second half of 2023 for a Regulation on chemicals data that will improve accessibility to information on chemicals;
- Perform an analysis, as part of the roadmap, of ways to accelerate the validation and acceptance of new non-animal methods;
- Analyse the possible need and feasibility of an expert scientific committee to provide advice on the development of non-animal approaches and their uptake and use in the regulatory context;
- Analyse ways to improve outreach activities with non-EU partner countries and multilateral organisations, as well as to increase the visibility of EU agencies in relevant international forums.

Similarly, to reach the goal of modernising science, further development of non-animal methods is required. Therefore, the Commission will continue its strong support to the development of alternative approaches with appropriate funding. The Commission is also exploring the possibility of coordinating Member States activities in this field.

The Commission does not share the view that a legislative proposal is the right tool to reach the goal of phasing out the use of animals in research and education. Science has not yet progressed sufficiently to offer adequate non-animal solutions for understanding completely health and diseases or the biodiversity. Therefore, the Commission proposes to develop specific measures for accelerating the reduction of animal testing in science. These actions are outlined in section 3.3 in the area of research, education and training to further strengthen the efforts towards phasing out animal testing.

Finally, the Commission, through a proposed new ERA policy action, invites the Member States, acting within their powers, and in particular for research and educational purposes, to

step up their efforts to reduce animal methods and to actively participate in developing alternative approaches.

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For the Secretary-General

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