



Save Cruelty Free Cosmetics – Commit to a Europe without Animal Testing: Briefing following the European Citizens' Initiative (ECI)

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Introduction

This briefing has been prepared on behalf of the five animal protection NGOs campaigning at EU level to end the use of animals in testing (Cruelty Free Europe, Eurogroup for Animals, the European Coalition to End Animal Experiments, Humane Society International/Europe and PETA), in follow-up to the successful European Citizens' Initiative (ECI) '*Save Cruelty Free Cosmetics – Commit to a Europe without Animal Testing*' [1], which was declared valid on 25th January 2023 with 1,217,916 signatures and promoted by over 100 national organisations.

The ECI was launched in 2021 to address the urgent risk of an increase in animal use for research, regulatory testing and education as a consequence of new policy proposals. This, coupled with a lack of progress towards replacement of animals or meaningful reductions in numbers, made it necessary to take these widespread concerns directly to EU citizens.

The ECI identifies three specific objectives: protect and strengthen the ban on cosmetics animal testing, transform EU chemicals legislation, and elaborate a strategy to phase-out the use of animals in research, regulatory testing and education. Each objective addresses an immediate EU issue and proposes pragmatic solutions that have the potential to improve the well-being and health of EU citizens, while also strengthening animal welfare, and protecting the environment. All three objectives focus on the transition to innovative non-animal science to tackle complex societal challenges such as disease management, drug failure and uncertainty in chemical hazard assessment, while delivering economic benefits.

The EU has gained a reputation as a global leader in animal welfare by acknowledging animals as sentient beings in its Treaty, and by developing a vast body of animal welfare legislation. In particular, Directive 2010/63/EU on the use of animals for scientific purposes makes full replacement of animal testing its ultimate goal [2]. However, in the last decade alone, it is estimated that nearly two billion animals have been used worldwide in scientific experiments [3] that frequently cause pain and suffering, but rarely deliver on their main promise of better protection for human health [4,5].

In this context, the successful ECI 'Stop Vivisection' [6] called on the EU to propose a European legislative framework to phase out animal testing, highlighting the desire of more than 1.1 million EU citizens to change the way research and regulatory testing is conducted. However, the Commission's response to this ECI in 2015 [7] has fallen short of introducing meaningful changes. Statistical reports published by the European Commission show that the number of animals used for scientific purposes has not decreased significantly, but has remained relatively stagnant at an average of 7.4 million animals per year since 2017 [8]. Every year, an additional 9.5 million animals are bred and killed for scientific purposes without being used in actual procedures. Furthermore, the discrepancy between the numbers of animals used in testing for regulatory purposes presented in EU statistical reports and those presented by ECHA [9] shows that most animal testing for regulatory purposes (i.e. Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (REACH)) is conducted outside the EU.

The launch of the ECI '*Save Cruelty Free Cosmetics – Commit to a Europe without Animal Testing*' in 2021 was therefore deemed necessary as it is clear that the EU is still far from significantly reducing the use of animals and moving towards human-relevant animal-free science. EU research, innovation and education initiatives are not yet aligned with the priorities identified by forward-thinking experts [10-12], or EU reports, such as the Commission's Joint Research Centre reviews on advanced non-animal models in different disease areas [13]. Animals continue to be systematically required and used for regulatory testing [14], and researchers favour animal models that are still too often considered as the 'gold standard' [15]. Yet, pioneering scientists who propose non-animal strategies for safety assessment and testing of new therapies find limited

support to continue their research. In addition, many researchers believe that innovation can lead to breakthrough solutions, but they fear that by using new research models they may face difficulties in publishing their research in high impact journals, consequently threatening access to funds [16].

There is, however, significant evidence and growing public concern about the scientific limitations, predictive value and effectiveness of many animal-based models [17, 18]. For instance, results from animal studies have been shown to be highly inconsistent in the prediction of toxic responses in humans [19], and the clinical failure rate of new drugs and therapies has remained above 92% for the past several decades [20]. This means that not only is the misguided reliance on animals a significant factor that is hindering the discovery of effective treatments for human diseases [21], but also that current animal-based safety testing approaches are unable to provide the data needed to ensure a high level of human protection [22], potentially leaving harmful chemicals on the market and leading to significant adverse consequences for human health [23]. On the other hand, non-animal methods, which include for example sophisticated tests using human cells and tissues, advanced computer modelling techniques, and use of human data are often less time-consuming and costly than animal tests [24, 25], but more importantly, they are more effective and relevant in predicting potential adverse effects on human health [26, 27].

Recognising the limitations and drawbacks of animal-based methods, EU agencies, industry and academia are investing in and transitioning to more humane solutions for better health protection and a safer environment [28-31], something overwhelmingly supported by Members of the European Parliament and EU citizens [32-34]. However, tackling the health and environmental issues that threaten society today requires not only more humane solutions and out-of-the-box thinking, but also adequate funding, and governance solutions[35]. The existing legislation is not fully equipped to allow Member States, regulators and assessment bodies to meaningfully replace and reduce the use of animals for scientific purposes. The EU budget to support research and innovation has significantly increased over time, but funding provided for non-animal approaches has remained relatively unchanged [36]. In addition, researchers currently using *in vivo* tests who would like to innovate and transition to non-animal methods need the legal mandate and political landscape to do so [37].

Therefore, EU-wide coordination of policies, objectives and actions is needed to fully replace animal-based science, as well as political and legislative changes to shift the landscape towards the innovative opportunities for better and more humane research, development, education and safety science that are urgently needed.

ECI Objectives

1. Protect and strengthen the cosmetics animal testing ban

The European Union banned the testing of cosmetics products on animals in 2004, banned animal tests for cosmetics ingredients in 2009, and prohibited the sale of cosmetics relying on newly generated animal test data in 2013. However, as the safety assessment of chemicals and products for human health is undertaken in the EU under a variety of different regulatory bodies and legislation, there is continued animal testing for ingredients exclusively used in cosmetics despite the ban. To justify this violation, the European Chemicals Agency (ECHA) and the European Commission argue that animal testing is required to protect workers and the environment [38].

The wishes of citizens are clear: animals must not suffer and die for the sake of cosmetics. The EU cosmetics testing ban represented landmark progress and spurred an unprecedented scientific movement to develop and uptake animal-free methods. This progress should be further leveraged to demonstrate that the use of non-animal methods can be widely applied across a range of sectors, including, for example, the industrial chemicals sector for safety assessment purposes.

We therefore call on the European Commission to:

1. **Protect the cosmetics animal testing ban** by ensuring that new safety assessments for cosmetics ingredients imported into, manufactured in, or sold within the EU must rely exclusively on non-animal data, regardless of the purpose or location of testing;
2. **Strengthen the cosmetics animal testing ban** by initiating legislative change to achieve consumer, worker and environmental protection for all cosmetics ingredients without testing on animals at any time;

3. Ensure that any proposed legislative revisions to the classification and testing of cosmetics products and ingredients are **consistent with the cosmetics animal testing ban**; and
4. Ensure that any scientific evaluations related to the safety of cosmetics products are carried out **without recourse to new animal tests**.

To achieve these goals, we recommend to:

- Expressly include workforce exposure under the Cosmetics Regulation to clarify that the interpretation of “human health” includes workers involved in the manufacture and processing of cosmetics products and their ingredients;
- Mandate environmental toxicity assessment under the scope of the Cosmetics Regulation;
- Ensure consistency with the ban through upcoming legislative proposals, such as REACH; and
- Ensure that the independence and innovative position of the Scientific Committee on Consumer Safety (SCCS) is protected in the forthcoming legislative changes, due to its long-standing and valuable expertise in the evaluation of risk assessments based on non-animal methods.

2. Transform EU Chemicals Regulation

In 2020, the European Commission adopted its Chemicals Strategy for Sustainability (CSS), which sets out a new long-term vision for the EU's chemicals policy and aims to achieve a high level of protection for health and the environment [39]. In this context, the Commission recognises the importance of scientific innovation in meeting these goals, and is committed to reducing dependency on animal testing and supporting the development and use of non-animal approaches [40]. However, rather than reducing reliance on animal-based science and ensuring a pathway to more human-relevant and innovative non-animal science, new EU policy is likely to dramatically increase the number of animals [41]. For instance, it has been estimated that new *in vivo* tests for endocrine disruptors and polymers, two key chemical categories, will require an additional 5.1 to 6.6 million animals [42]. Continued reliance on animal testing would not only jeopardise the success of the CSS, but also undermine the EU's commitment to fully replacing the use of animals in regulatory testing.

To achieve the objective of ensuring sustainable chemicals regulation without recourse to additional animal test requirements, we urge the Commission to ensure that, at a minimum, the following mandates are met:

- 1. Put in place concrete steps to develop and implement non-animal approaches** to identifying toxic chemicals via dedicated resources, meaningful timelines and fully enabled, cross-sectoral support. We emphasise that "implementation" includes the active deployment of regulatory decision making based on innovative data which is not equivalent to animal-derived information and therefore avoids comparison to a flawed system;
- 2. Ensure rapid uptake of non-animal approaches**, with alignment across European agencies with administrative responsibility for chemicals, biocides, plant protection products, pharmaceuticals, and other products; and
- 3. Ensure that default recourse to unreliable animal testing to supply chemical data at the expense of full scientific consideration of all available approaches is not permitted under both current and future European regulations.**

To meet the minimum mandates, we recommend to:

- Create a dedicated expert scientific committee on the application of non-animal methods to safety assessment, similar to the role of the SCCS, to provide independent advice and recommendations to the registrant on suitable non-animal methods for specific endpoints, and provide input into any reviews of current practice and any update or revision of regulations;
- Commit to implementing non-animal methods while moving away from animal testing. In revising the two interacting flagship chemicals regulations, REACH and the Classification, Labelling and Packaging regulation (CLP), the Commission should seize the opportunity to ensure that the legislative language used for classification criteria and information requirements is flexible enough to accommodate the most technologically advanced non-animal methods. This is also in line with the Commission's recent announcement of a European roadmap aiming to fully replace animals in chemical safety assessments [43]; and
- Commit to no further new or expanded animal testing requirements. This is the ultimate way to achieve the ambitious goals of the CSS while respecting humans, the environment, and animals.

3. Modernise science in the EU

The EU has some of the most advanced legislation in the world to protect animals used for scientific purposes. Directive 2010/63/EU not only sets the ultimate goal of completely replacing all scientific procedures on animals, and aims to minimise animal use. In addition, European citizens have consistently demonstrated support for an end to the use of animals for scientific purposes. A recent opinion poll revealed that 77% of EU citizens agree that the European Commission and its Member States should develop a coordinated strategy to transition to scientific research, testing, and education without the use of animals [34].

The transition to non-animal science has been recognised as an important step towards improving health and environmental protection and finding effective treatments for disease. The European Commission itself has acknowledged that animal-based research is not delivering solutions to human health problems. For example, recent reviews into respiratory tract and neurodegenerative diseases published by the Commission's Joint Research Centre have respectively emphasised that *"The lack of effective new therapies for serious respiratory conditions like asthma indicate that reliance on animal models is failing to identify pathways to novel treatments"* [44], and *"The failure rate of drug development for Alzheimer's disease is 99%, and the last new medicine was approved in 2003. One reason for this high failure rate is the poor translation of research results obtained using animal models to the human situation"* [45].

Yet, the number of animals used for scientific purposes is not decreasing significantly. This is due to a lack of effective measures to facilitate the transition. Animal-based models are still too often considered as the 'gold standard', and weaknesses in the design, conduct and reporting of research involving animals are well documented, but continue to persist [17]. In addition, researchers who are willing to contribute to solving societal problems through innovative solutions and technologies still lack adequate and sufficient incentives to do so. The failure to translate findings from animal-based studies to human clinical trials, and the lack of reproducibility of much animal research need to be better addressed, and more funds should be made available for non-animal research, while the funding of animal-based research should be re-evaluated.

Therefore, we call on the Commission to 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. In particular, we urge the Commission to ensure that, at a minimum, the following mandates are met:

1. Openly endorse the desirability of phasing out the use of animals in science, while also acknowledging that Directive 2010/63/EU does not in and of itself represent a roadmap towards full replacement;
2. Prioritise the development and validation of non-animal methods in the EU budget and new initiatives, policies and frameworks;
3. Coordinate actions across the directorates-general, agencies and Member States to achieve a strategic focus on the final goal of fully replacing the use of animals in scientific procedures; and
4. Include in the legislative proposal achievable science-based targets for the reduction of animal use, investment in advanced non-animal approaches and infrastructure, synergy in education and training, and regulatory acceptance of non-animal methods.

To meet the minimum mandates, we recommend to:

- Establish EU-wide collaboration and coordination, similar to the coordination of strategies and goals under the European Research Area, for example [46];
- Establish clear milestones on issues such as policy challenges, investment needs and opportunities in different sectors to focus minds and drive activities towards the desired goal, as has been done in other areas of societal concern (e.g. climate emergency, healthcare and education);
- Identify key research areas of concern in consultation with EU Member States and stakeholders to analyse the continued use of animals in these areas and determine mechanisms to direct focus and funding to promote the replacement of animals in these areas;
- Assess and expand key infrastructure that can allow for fuller exploitation of existing and new non-animal technologies. Strategic funding for the creation of 'hubs' where researchers from different institutions can share or rent equipment that would allow them to exploit non-animal technologies at a far cheaper cost, would significantly increase access and thus uptake;

- Redirect funding and resources towards non-animal science to address the lack of level playing field between the funding of research involving animals and the development of new advanced non-animal technologies;
- Support education and training initiatives to help students, researchers, educators, and regulators to change their working practices, and have the knowledge, skills and confidence to embrace biologically-relevant, animal-free methods; and
- Improve project evaluation and authorisation processes, as well as peer review and publication policies from scientific journals. Decisive and immediate steps need to be taken to stop poorly designed, executed, analysed and reported science involving the use of animals from being funded and licensed, approved by reviewers and being published.

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Conclusion

EU citizens continue to express their dissatisfaction with what they see as insufficient action to transition to non-animal science. After the first ECI 'Stop Vivisection' in 2015, a second ECI collected again more than one million signatures in 2022. The ECI '*Save Cruelty Free Cosmetics – Commit to a Europe without Animal Testing*' was promoted by 100 national organisations and their supporters as well as global cruelty-free brands including Dove and The Body Shop.

Each of the objectives of the ECI responds to a direct EU threat while also offering solutions that have the potential to improve the protection of human health and the environment, and to strengthen animal welfare. The objectives recognise the need for immediate action as well as identification of medium- and long-term goals, and we are keen to engage further, as we do through the European Partnership for Alternative Approaches to Animal Testing (EPAA), through our numerous stakeholder positions, and internationally through our input at the Organisation for Economic Co-operation and Development (OECD) and (more recently) the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS).

We believe it is time for the EU to stop relying on animal testing and commit to a future based on better and more humane science and education. The European Commission has the opportunity to be the main driver of this transition, to the benefit of humans, science, animals, and the environment. Therefore, we hope that the European Commission will provide the necessary leadership to create the conditions in which scientifically relevant, animal-free research, education and regulatory testing in the EU will thrive and grow.

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