

Reducing and replacing animal experiments: Europe needs an action plan

The EU considers itself a world-leader in innovation, safety and animal welfare, but its continued reliance on animal testing undermines this status and threatens to see Europe left behind compared to other regions. At least **23.5 million animals are bred and killed in EU laboratories every year**, and this staggeringly high number is **dropping by only 1% on average each year**. At the current pace, animals will continue to suffer in EU laboratories until the year 2126.



This slow rate of change is **at odds with public and political will** – citizens¹ and the European Parliament² overwhelmingly support development of an action plan to speed up the transition to animal-free research and regulatory testing in the EU. Aside from ethical objections and well-founded concerns for the welfare of animals in laboratories, many are now recognising that **animal tests are slow**, **unreliable and costly**, wasting resources and impeding scientific progress. A move away from reliance on animal tests would ensure citizens have access to the best choice of safe and effective medicines and other products. We cannot afford to wait another hundred years for this to happen – **the EU needs an action plan to phase out animal testing, and it needs it now.**

Animal tests prevent scientific progress

Drug development is in crisis: **92% of drugs fail in human clinical trials despite testing safe and effective in extensive animal tests.**³ This failure of animal "models" to correctly predict human responses contributes to the huge amount of time (up to 15 years) and money (\$2.6 billion) it takes to bring a new drug to market,⁴ resulting in fewer safe and effective medicines for those who need them. Researchers desperately need a better way of accurately predicting human responses, and that's where non-animal methods (NAMs) come in.

Unlike animal tests, NAMs use human-relevant approaches like three-dimensional cell culture, genetic analysis and sophisticated computer simulations to understand biological processes or predict how a substance will interact with the cells and proteins in a human's body. **NAMs are already widely used** in areas including respiratory disease and breast cancer research and are **outperforming animal tests** in their ability to identify substances that may cause allergic skin reactions⁵ or damage the liver.⁶

The public does not support animal tests

In a 2020 poll of EU citizens across 12 member states, 72% agreed that Europe should set

targets and deadlines to phase out animal testing, 70% agreed that replacing animal tests with non-animal methods should be an EU priority and 66% agreed that the EU should immediately end all animal tests.⁷ 1.17 million EU citizens supported the "Stop Vivisection" European Citizens' Initiative, while a petition to close a German animal testing facility following a 2019 exposé gained over a million signatures within just a few weeks.

The public evidently has only limited backing for animal research, is opposed to much of the testing that takes place in the EU and supports a proactive phase out strategy.

Current provisions are not enough to phase out animal tests

One of the stated goals of Directive 2010/63/ EU, which sets minimum standards for the use of animals in laboratories, is to fully replace animal testing. While we support this goal, it is difficult to see how it will be achieved without an action plan (which the Directive fails to provide) and sufficient funding (which the Commission and Member States fail to provide; for example, projects developing alternatives to animal testing received just 0.1% of Horizon 2020's budget).⁸ led to clinical benefit despite years of effort.

- 2. "Curiosity-driven" or "blue skies" research that uses animals without even intending to generate direct benefits for society.
- 3. Duplicated lack of a central repository for animal studies, and hesitancy to publish negative results, means that researchers unknowingly duplicate each other's work.
- 4. Replaceable or redundant over 1.6 million animals are used each year in the EU in regulatory tests that have already been replaced by non-animal methods or are no longer required by law.
- "Surplus to requirements" almost a third of animals bred in EU laboratories (over 6 million animals in 2017) are killed without ever being used in experiments.¹⁰

Directive 2010/63/EU and some sector-specific regulations (for example, industrial chemicals legislation) contain provisions designed to minimise tests on animals and promote alternatives, but they are not functioning properly and are no substitute for an action plan – complete with measurable targets and timelines – to phase out animal testing in the EU. Policymakers recognise in other important

Additionally, focusing on replacement supports the misconception that all animal tests are worth replacing. In reality, very few (if any) of the 23.5 million animals used each year across the EU are essential to scientific progress. Ending most animal uses immediately and without replacement would be of no detriment to society, because they are:

 Scientifically flawed

 animal "models" of human diseases like
 Alzheimer's⁹ have not



areas including carbon emissions and pollution that **targets and timelines are crucial tools for achieving change, so why not use them when it comes to animal testing?**

The solution: an action plan to accelerate the transition to animal free research and regulatory testing

To maintain its status as a world-leader in innovation, safety and animal welfare, **the EU needs an action plan, complete with targets and timelines, for phasing out animal testing.**

We urge the European Commission to:

- Establish a high-level inter-service taskforce and a Commissioner for Animals to develop and deliver the plan in close collaboration with Member States and other stakeholders.
- 2. Embed the goal of reducing and replacing animal experiments into horizontal European Union priorities like the Green Deal, innovation and post-COVID recovery plans.
- Instigate a full review of Directive 2010/63/EU to assess its impact and identify where significant change could be made
- 4. Conduct **thematic reviews**, as mandated by Directive 2010/63/EU, to identify priority areas for reduction and replacement of animal use.
- 5. Propose changes to Directive 2010/63/ EU and sector-specific legislation to prohibit, by a given date, certain types of experiments such as those causing severe suffering, and set targets for reducing animal use generally.
- 6. Propose changes to Directive 2010/63/ EU and sector-specific legislation to clarify Member States' obligation to contribute to the promotion of NAMs and ensure that animal testing is only ever conducted as a

last resort.

- 7. Increase funding and support for NAMs research (within the Horizon Europe, pilot project schemes and other relevant frameworks) and EU bodies responsible for validating and promoting alternatives to animal testing (including the EU Reference Laboratory for Alternatives to Animal Testing, DG Environment and the European Partnership for Alternative Approaches to Animal Testing).
- 8. Give **EU agencies** a clear mandate and resources to promote alternatives to animal tests.
- 9. Improve **enforcement** of Directive 2010/63/ EU and sector-specific legislation.
- 10. Ensure that **animal tests for which there are already valid alternatives** in place are not being used in member states.

For more information, please visit www.crueltyfreeeurope.org



1 Savanta: ComRes. Cruelty Free Europe – Animal Testing in the EU. 2020. Available at: comresglobal.com/polls/crueltyfree-europe-animal-testing-in-the-eu/

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4 DiMasi JA et al. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016;47:20-33. doi:10.1016/j.jhealeco.2016.01.012

5 Kleinstreuer NC et al. Non-animal methods to predict skin sensitization (II): an assessment of defined approaches. Crit Rev Toxicol. 2018;48(5):359-374. doi:10.1080/10408444.2018. 1429386.

6 Dirven H et al. Performance of preclinical models in predicting drug-induced liver injury in humans: a systematic review. Sci Rep. 2021;11:6403. https://doi.org/10.1038/ s41598-021-85708-2

7 Savanta: ComRes. Cruelty Free Europe – Animal Testing in the EU.

8 Public Impact Limited. Research into and promotion of alternatives to animal testing in the EU Budget and prospects for the 2021-27 MFF (Report Prepared for Cruelty Free International). 2020. Available upon request.

9 Alteri E, Guizzaro L. Be open about drug failures to speed up research. Nature. 2018;563(7731):317-319. doi:10.1038/ d41586-018-07352-7.

10 European Commission. Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council on the implementation of Directive 2010/63/ EU on the protection of animals used for scientific purposes in the Member States of the European Union (SWD(2020) 15 final). 2020. Available at: ec.europa.eu/environment/chemicals/ lab_animals/pdf/SWD_Implementation_report_EN.pdf