

The World-Leading EU Cosmetics Animal Testing and Marketing Bans

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. At this point, consumers, companies, and animal protection organisations rightly claimed a groundbreaking victory resulting from decades of campaigning. These bans have since been held up as the gold standard for animals around the world, and in 2018, their significance was reinforced when the European Parliament overwhelmingly supported a call for a global end to cosmetics testing on animals. Now, this hard-fought progress is being substantially weakened by the current stance of the European Commission and the European Chemicals Agency (ECHA).

Circumventing the Bans

A series of testing decisions by ECHA made with the policy backing of the European Commission, along with recent decisions by the ECHA Board of Appeal, have challenged a basic principle of interpreting EU legislation by disregarding the clear intent of legislators and thereby seriously undermining the cosmetics testing bans.

The European Commission and ECHA issued a joint statement announcing that they're still insisting on animal testing under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation for chemicals used exclusively in cosmetics for which there is a possibility of workforce exposure during the manufacturing process or a risk to the environment.

For ingredients that are used in cosmetics as well as other types of products, tests on animals are required without the justification of potential workforce exposure or environmental risk, suggesting that the REACH Regulation overrides the EU Cosmetics Regulation animal testing ban. It should also be noted that neither the cosmetics nor REACH regulations make a distinction between exclusive-use and dual-use cosmetics ingredients.

In addition, the European Commission's Chemicals Strategy for Sustainability (CSS)¹ is set to re-open the Cosmetics Regulation, with the potential to introduce new testing requirements at the expense of many more animals' lives.

Devastating Impact on Animals' Lives

Already, thousands of animals are being condemned to suffer in additional testing of existing cosmetics ingredients that have been manufactured and marketed safely under EU cosmetics legislation for decades. The bans that animal advocates fought so hard to achieve – and that the public and scientists overwhelmingly support – are effectively being rendered meaningless.

Bringing a Product to Market Without Testing on Animals

It is imperative that the purpose of prohibitions contained within the Cosmetics Regulation – that cosmetics products be safely brought to market without new animal tests – be properly applied. For ingredients marketed under the Cosmetics Regulation that have a history of safe use by consumers and of controlled handling on the factory floor, robust protection of both workers and consumers is already enabled through a variety of non-animal assessment methods and careful application of exposure assessments. When regulators decide that a new ingredient cannot be brought safely to market without animal testing, its introduction should be delayed until additional non-animal test methods are available. The Commission accepted this in a public statement in 2013.²

Cosmetics Tested Under REACH – It’s Time to Come Clean

Continued requests for new animal testing of existing cosmetics ingredients under REACH are set to impose severe limitations on the availability of products and ingredients marketed within the cruelty-free sector. The European Commission must come clean to consumers and parliamentarians about the consequences of its stance on the integrity of the bans and animals in laboratories. European consumers expect to be able to buy cosmetics that have not been tested on animals, and the European Commission and ECHA have a duty to ensure that this is the case by applying the law properly.

OBJECTIVE 1

We call on the European Commission to 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.

The wishes of citizens and legislators are clear: animals must not suffer and die for the sake of cosmetics. We maintain that new safety assessments for cosmetics ingredients imported into, manufactured in, or sold within the EU may only rely on non-animal data. As such, EU test requirements – including requirements set out in REACH – must not undermine the bans. Instead, a substance-tailored approach should be applied to ensure consumers, workers, and the environment are protected without further tests on animals. It is essential that the European Commission ensure proper implementation of the bans on animal testing for cosmetics and on marketing animal-tested products as originally intended and instigate legislative change to achieve this goal for both human health and environmental toxicity endpoints across all relevant sectors.

To achieve the objective of protecting and strengthening the cosmetics animal testing ban, we urge the European Commission to ensure that the following mandates are met:

- Immediately implement the existing EU bans on animal testing for cosmetics and the marketing of ingredients tested on animals as intended by legislators to ensure that only non-animal methods are used for the safety assessment of cosmetics ingredients.
- Clarify that the requirement to rely on non-animal data for the safety assessment of cosmetics ingredients must be applied and animal data rejected, regardless of the location and purpose of animal tests conducted after the cut-off periods described in Article 18(2) of the EU Cosmetics Regulation.
- Initiate legislation to strengthen and broaden the cosmetics testing bans to ensure that consumers, workers, and the environment are protected without new tests on animals.
- Devise a robust testing strategy for cosmetics ingredients using only available non-animal assessment strategies so that the implementation of the Chemicals Strategy for Sustainability reflects the overwhelming support for strengthening – rather than weakening – the protection of animals in Europe.

Transforming Chemicals Regulation

The European Commission's [Chemicals Strategy for Sustainability](#) presents a new long-term vision for the EU's chemical policy. In line with the [European Green Deal](#), the CSS sets out a vision for a toxic-free environment – aiming to better protect citizens and the environment and boost innovation for safe and sustainable chemicals through a number of planned actions. These include banning hazardous chemicals in consumer products and allowing their use only where essential, accounting for the cocktail effect of chemicals when assessing risks from chemicals, boosting the investment in and innovative capacity for the production and use of chemicals that are safe and sustainable by design and throughout their life cycle, and establishing a simpler “one substance, one assessment” process for the risk and hazard assessment of chemicals.

Whilst aiming to achieve a worthy goal, the CSS presents a number of significant concerns with regard to the use of animals in regulatory chemical testing. Without urgent action, the Commission's proposals are likely to result in new tests on millions of animals, further weaken the cosmetics animal testing ban in the EU, and undermine the goal of replacing all animal experiments, as expressed in Directive 2010/63/EU on the protection of animals used for scientific purposes.

Continued Dependence on Unreliable Animal Tests Will Harm Safety

Ironically, since tests on animals are known to lack reliability, relevance, and – in the case of those designed to detect certain carcinogens and endocrine disruptors – validation to modern standards, basing regulatory and chemicals management decisions on the results of such tests could lead to the misclassification of substances and, consequently, the failure to achieve the Commission's goal of a toxic-free environment. Indeed, it would be a betrayal of the European Green Deal to take a tick-box approach to fulfilling standard animal test requirements that consequently limits opportunities to improve protection of humans, the environment, and animals.

Animal tests are designed to measure the effects of large doses of single substances administered to small animals with short lifespans. They cannot address the long-term effects of the cocktail of low doses of chemicals to which human beings – large animals with long lifespans – are exposed. In addition, species differences render animal tests intended to identify subtle effects such as disruption to human endocrine or immunological systems or neurobiology, especially from low doses of substances, highly unlikely to meet their intended objective.

Consider, for example, studies conducted using rats or mice to assess whether a chemical causes cancer in humans or not. The rodent cancer bioassay has come under scrutiny since the 1970s for its inability to predict human outcomes. Two assumptions underlie the bioassay: (1) rodent carcinogens are human carcinogens, and (2) high-dose chemical exposure in rodents is indicative of an environmentally relevant dose.³ Both assumptions have been proved incorrect by 50 years' worth of data. The test also lacks predictivity and is poorly reproducible, with factors such as stress, differences in diet, and even the strain or sex of test animals likely to affect results.^{4,5,6} One review found a concordance of only 57% in carcinogenicity classifications for duplicate studies.⁷

Non-Animal Methods Provide Opportunities to Optimise Human and Environmental Safety

Politicians, advisory groups, regulators, industry, and health advocates now acknowledge that many animal tests are limited and that there is an urgent need for more reliable, human-based data.

Non-animal methods – which include sophisticated tests using human cells and tissues, advanced computer modelling techniques, and studies with human volunteers – often take less time and money to complete than animal tests, but more importantly, they are more effective and relevant for predicting potential adverse effects on human health and the environment. For example, a standard test using pregnant animals to find out if a substance may harm a developing baby can only detect approximately 60%⁸ of dangerous substances, but a cell-based method using animal stem cells has 88%⁹ to 100%¹⁰ accuracy, with work currently in progress to develop methods using human stem cells.¹¹ Consider also the notorious Draize test used to predict skin irritation, in which chemicals are typically applied onto the shaved skin of rabbits to check for the severity of the reaction, after which the rabbits are killed. The test can only predict human skin reactions 56% of the time,¹² but methods using reconstituted human skin are up to 86% accurate.¹³ Likewise, non-animal approaches have greatly improved our ability to predict which substances might cause a skin allergy.¹⁴ By relying on human cells and tissues, safety assessors and regulators are not hindered by species differences that make applying animal test results to humans difficult.

The advent of the cosmetics testing and marketing bans saw a boom in the development and application of non-animal methods that can be broadly applied across a range of sectors – including the industrial chemicals sector – for safety assessment purposes. By replicating the model for increased investment set to strict objectives and milestones, an animal-free regulatory framework, once perceived as impossible, can be achieved.

OBJECTIVE 2

We call on the European Commission to transform EU chemicals regulation.

Ensure human health and the environment are protected by managing chemicals without the addition of new animal testing requirements.

The European Green Deal introduces a worthy commitment to a toxic-free environment whilst also presenting a golden opportunity for modern and sustainable regulation of chemicals. With the right investment and careful design, the EU could use non-animal approaches to provide the best protection of human health and the environment without wasting resources on an over-burdened and unreliable system dependent on the suffering and death of animals.

To achieve the objective of ensuring sustainable chemicals regulation with recourse to additional animal test requirements, we urge the Commission to ensure that, at a minimum, the following mandates are met:

- Put in place concrete steps – with dedicated funding, ambitious timelines and cross-sectoral support – to develop, validate, and implement human-relevant, non-animal approaches to identifying toxic chemicals.
- Ensure that the rapid uptake of non-animal New Approach Methodologies is aligned between the European agencies with administrative responsibility for chemicals, biocides, plant protection products, pharmaceuticals, and other products.
- 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.

Modernising Science in the EU

Over 10 million animals were used in scientific procedures in EU laboratories in 2017¹⁵ (the most recent figure available), and over three-quarters of those animals were used in tests not designed to meet regulatory requirements. It is therefore crucial to address areas of animal use beyond regulatory testing for the EU to achieve its final goal of fully replacing live animals in scientific and educational procedures.¹⁶

Moving Beyond the Status Quo

Directive 2010/63/EU on the protection of animals used for scientific purposes recognises that the final goal is to replace all scientific procedures using animals for research, education, and regulatory testing. However, the notion that tests on animals must only be replaced once non-animal methods are in place contradicts current scientific knowledge and best practices. The limited validity of animals to model human diseases or predict toxicological endpoints must urgently be addressed. The lack of translational value and/or reproducibility of much of the animal research currently being carried out is well publicised.^{17,18} Yet, funding continues to flow for the use of such models and tests, and projects involving them continue to be authorised and published, often with an overestimation of the benefits of the treatment studied and limited retrospective evaluation that erroneously feeds into the rationale for the continued cycle of animal use.¹⁹ This should stop.

The Need for a Commitment to Phase Out Tests on Animals

If our public funds are to be used responsibly, they must fund research that leads to effective human health, environmental protection, and animals' well-being. As such, there is a need for a significant reconsideration of research and funding priorities. Whilst the provision of additional funding alone will not provide the solution, funding is nevertheless a significant limiting factor in the ability to attract wider activity in this area and make faster progress towards non-animal science. The amount of money spent on non-animal models may have increased in recent years, but it is still dwarfed by the amount made available for research involving the use of animals. This is insufficient to achieve the rate of transformative change required.

As seen through the Cosmetics Regulation, setting a date by which non-animal methods must be used incentivises and hastens the development of such methods. Setting target dates is not a new concept in EU policy. Take, for example, targets for climate change, greenhouse-gas emissions, and gender equality. Such milestones help to focus minds and motivate and drive activities towards the desired goal. The goals should be ambitious, challenging, and far-reaching but also realistically achievable.

Although Directive 2010/63/EU establishes the objective of ultimately ending the use of animals for scientific purposes, the Commission has yet to create a dedicated framework within which to do so. To date, the implementation of Directive 2010/63/EU serves to regulate rather than end animal suffering; it is not a strategy for phasing out tests on animals. A successful phase-out of all animal testing requires an EU-wide action plan including an appropriate level of funding to support the development and uptake of new, advanced non-animal technologies; identification and prioritisation of key research areas where resources and efforts need to be targeted; large-scale support for building key infrastructure that would allow for fuller exploitation of existing and new advanced non-animal methods; clear milestones; and education and training in non-animal technologies.

OBJECTIVE 3

We call on the European Commission to 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.

The EU is at a crossroads. Decision-makers can choose either to continue relying on archaic animal tests or to lead the world by fostering a new era of animal-free science. Seventy-two per cent of adults in EU member states agree²⁰ that the time is right for the EU to plot a roadmap – containing concrete, measurable targets with associated timelines – towards its final goal of ending animal tests.

To achieve the objective of working towards a roadmap for the phase-out of all animal testing in the EU, we urge the Commission to ensure that, at a minimum, the following mandates are met:

- Openly endorse the desirability of phasing out the use of animals in science and state the belief that this is achievable. To illustrate this commitment, prioritise a transition to non-animal approaches as an integral part of all EU research, innovation, and education initiatives, while also acknowledging that Directive 2010/63/EU does not in and of itself represent a roadmap towards full replacement.
- Prioritise the development and validation of non-animal methods in the EU budget and new overarching policies such as the European Green Deal, the Chemicals Strategy for Sustainability, and post-COVID recovery plans and redirect funding away from animal studies to alternatives.
- Coordinate actions across the directorates-general and agencies responsible for aspects of research, regulatory testing, education, and funding with the involvement of all member states to achieve a strategic focus on the final goal of fully replacing the use of animals in scientific procedures.
- Include in the legislative proposal ambitious and achievable science-based targets with regard to a 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.

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