REACH revision must align with the EU's commitment to ending animal testing


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The EU has committed to ending animal testing for chemical safety assessment – a pledge driven by the Chemicals Strategy for Sustainability (CSS),[1] the European Parliament's 2021 resolution concerning the CSS,[2] and the response to the EU Citizens' Initiative "Save Cruelty Free Cosmetics – Commit to a Europe Without Animal Testing".[3] To deliver on this commitment, the REACH revision must prioritise non-animal methods as the new standard for chemical safety assessment.

While innovative, non-animal methods hold the promise of equal or higher protection, the current system hinders their uptake.[4,5] The REACH revision provides a pivotal opportunity to lead globally by transitioning to humane and science-based safety assessments.

To fully align with the EU's goal of ending animal testing, six key reforms are urgently needed:

1. CLOSE THE COSMETICS TESTING LOOPHOLE.

Align REACH with the EU's landmark ban on animal testing for cosmetics enacted under the Cosmetics Products Regulation (CPR).[6]

- **Use CPR data for REACH:** Consider exposure information and non-animal safety data submitted under the CPR to fulfil REACH requirements.[7]
- **Restrict animal testing for cosmetics ingredients to exceptional cases** in line with the derogation clause contained within the CPR following stakeholder consultation and based on robust scientific justification.
- **Advance non-animal methods for environmental safety:** Support the development, implementation, and regulatory acceptance of non-animal methods, expanding approaches such as Next Generation Risk Assessment to environmental safety assessment.[8]


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2. STRENGTHEN THE LEGAL FRAMEWORK TO PROMOTE NON-ANIMAL METHODS.

A revised REACH Regulation must maximise the use of predictive and valid weight-of-evidence approaches, computational models, and toxicology tools as primary data sources.[9]

- **Amplify the requirement to test on animals as a last resort throughout REACH** to mandate a stepwise testing strategy requiring the use of available adaptations before any animal test is proposed and documenting evidence to justify additional testing.
- **Empower ECHA and Member States** to verify that submitted information strictly adheres to the last resort requirement.
- **Base test requirements on clearly defined information needs** demonstrating the potential risk to human health or the environment, that the risk needs to be

clarified, and that the requested test will improve risk management.

- **Actively promote non-animal methods** to replace tests on animals and to make regulatory decisions to avoid triggering new tests on animals.

3. FUTURE-PROOF REACH AND UNLOCK INNOVATION.

To reflect the state of the art in chemical safety assessment, REACH must be equipped with simplified mechanisms that allow for the timely integration of new non-animal approaches.

- **Introduce a science-driven framework** by replacing specific test mandates with the broader information objectives that must be met and supported by technical guidance to ensure legal certainty.
- **Require annual reviews and updates of technical guidance** through a transparent, science-driven process, with a clear obligation to accelerate the integration of non-animal methods within REACH.
- **Support ECHA and competent authorities with regular training** to maintain up-to-date expertise on the application of non-animal approaches. Directive 2010/63/EU sets a precedent by mandating minimum standards for training and competence in animal use.

4. MODERNISE REACH COMPLIANCE TO PUT NON-ANIMAL METHODS FIRST.

Ensure that REACH registration and compliance processes prioritise the use of non-animal methods and avoid defaulting to tests on animals.

- **Require tiered strategies in testing proposals:** Testing proposals must be required for all animal tests and follow a tiered, exposure-driven approach, applying all available non-animal methods first.
- **Demand clear evidence that non-animal methods were fully considered:** When no suitable non-animal option has been identified, a detailed justification must be provided before any animal test is conducted.

- **Strengthen compliance checks:** Empower ECHA to request non-animal adaptations, clarify that registrants can update their dossiers throughout regulatory processes, and ensure that changes to tonnage bands are considered to prevent outdated justifications for new tests on animals.

5. BOOST TRANSPARENCY—CUT WASTE, REDUCE COSTS, AND ACCELERATE NON-ANIMAL INNOVATION.

Prevent redundant animal testing and accelerate the uptake of non-animal methods.[10]

- **Encourage post-exclusivity data sharing:** Make robust study summaries usable after the exclusivity period expires to enhance non-animal approaches such as read-across.
- **Track and report the use of non-animal methods annually:** Ensure that reports and suitable metrics for tracking progress are used to identify opportunities for improvement.
- **Mandate reporting the date and location of all submitted animal tests:** Verify compliance with EU standards and uphold public trust.
- **Align REACH with "one substance, one assessment":** Ensure that data flows across regulatory frameworks through a common set of tools and reporting standards and ensure that publicly funded research, such as from Horizon Europe and PARC, is used.

6. CREATE AN EXPERT COMMITTEE TO DRIVE SMARTER, FASTER ADOPTION OF NON-ANIMAL METHODS.

REACH must be supported by a body of independent experts, akin to the Scientific Committee on Consumer Safety, to ensure consistent, science-based implementation of the requirement to test on animals as a last resort and accelerate the regulatory acceptance of non-animal methods.

- **Guide regulatory acceptance:** Empower the committee to advise on scientific guidance updates and regulatory acceptance procedures, accelerating the uptake of non-animal methods across all endpoints.
- **Strengthen oversight:** Task the committee to support ECHA by evaluating justifications for animal testing, contributing to the annual report on non-animal method uptake, and identifying opportunities to eliminate redundant tests.
- **Serve as a safe space for discussion:** Facilitate stakeholder discussions to collaborate on non-animal approaches without penalty.
- **Build expertise and leadership:** Instruct the committee to identify education and training needs and promote targeted capacity-building so that regulators, industry, and researchers stay ahead in using the best science.

By adopting these reforms, the EU would uphold its commitment to ending animal testing, supporting scientific innovation, and delivering high levels of protection for human health and the environment.

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