Briefing

on the request for an EP Motion for a Resolution calling for a coordinated Union-level action plan to facilitate the transition to innovation without the use of animals in research, regulatory testing and education

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Introduction

The five animal protection groups – Cruelty Free Europe, Eurogroup for Animals, the European Coalition to End Animal Experiments, Humane Society International/Europe and PETA – which together represent over 100 member organisations from 26 EU member states, strongly support the introduction of an oral question with motion for resolution calling for an EU Action Plan to phase out animal testing. Opinion polling carried out in June 2020 shows that **nearly three quarters (72%) of adults in EU member states agree that the EU should set binding targets and deadlines to phase out testing on animals.**

Present context: a lack of progress in replacing the use of animals in experimentation in the EU.

When adopted, Directive 2010/63/EU on animal experimentation raised hopes that scientific research in the European Union would transition towards non-animal methods, and progressively turn the page on ethically and scientifically questionable animal experimentation. In its recitals, the Directive claimed to be “an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes”. Ten years on, the European Commission’s statistics on animals used for scientific purposes tell a different story. Progress has stalled: since implementation of the Directive from January 2013, the number of animals used in experimentation went from 9.5 million in 2015, to 9.8 million in 2016 and 9.3 million 2017, with a yearly average of 9.6 million per year.

Why is the number of animals used in experiments not going down?

Directive 2010/63/EU sets common European rules for animal welfare, qualification of personnel, administrative authorizations and reporting, but contains few provisions to promote non-animal methods. The slow uptake of validated alternatives in regulatory

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2. Recitals 10 and 11 of Directive 2010/63/EU.
testing\textsuperscript{4} contributes to these disappointing statistics, despite specific provisions in REACH (Regulation (EC) No 1907/2006) to promote alternative methods and only use animals as a last resort.

Demands from the European Chemical Agency (ECHA) for animal testing of ingredients used exclusively in cosmetics are particularly disappointing, causing the consternation of millions of citizens in Europe who genuinely believed that Cosmetics Regulation (EC) No 1223/2009 had banned this practice.

Yet, the rapid emergence of advanced non-animal models such as organs-on-a-chip, pathway-based approaches and computer models today offer immense opportunities to replace animals and improve research. The Joint Research Centre has listed many of these methods for several disease areas\textsuperscript{5} but, again, these reports have not been followed by concrete actions. We believe that an Action Plan is urgently needed to turn the replacement of animals in scientific procedures into a priority for the EU.

Why is an Action Plan needed?

An Action Plan sets a series of steps to reach concrete objectives. The main features are: scope, time horizon and resource allocation. Today the EU does not have a comprehensive policy program to phase out and replace animal experiments encompassing the objectives of existing EU legislations and funding instruments.

This is why an EU Action Plan to accelerate the transition to innovation without the use of animals in research, regulatory testing and education is necessary and urgently needed. By requiring the Action Plan - like already done for many other policy areas - the European Parliament has the opportunity to ensure that the EU will be equipped with clear means and targets to ensure that the objectives of existing legislation will be attained.

What would be the main objective of the Action Plan?

To elaborate a roadmap for comprehensive and multi-disciplinary proposals with specific goals and timetables for phasing-out reliance on the use of animals in research, regulatory testing and education in the EU.

What measures could the European Commission undertake as part of an Action Plan?

The European Commission has multiple policy and financial levers at its disposal to curb the use of animals in science, and replace their use with non-animal methods:

\begin{itemize}
  \item \textsuperscript{4} [https://www.altex.org/index.php/altex/article/view/1755/1722]
  \item \textsuperscript{5} Including breast cancer, respiratory tract diseases and neurodegenerative diseases. [https://ec.europa.eu/jrc/en/eurl/ecvam/knowledge-sharing-3rs/life-science-research]
\end{itemize}
• **Funding:** Under Horizon Europe and other research and innovation initiatives, funding of scientific projects making use of advanced non-animal models could be increased and prioritized.

• **Training:** Advanced non-animal models sometimes require specific training and multidisciplinary competences. The Commission could work together with Member States to promote the key competences, and knowledge required.

• **Chemicals:** The Commission already has the power and duty to ensure effective implementation of existing regulations that deal with the safety of chemicals, and other products. In consultation with relevant agencies, the Commission can set reduction objectives through a more proactive implementation of these regulations.

• **Private sector:** Through the European Commission Pharmaceutical Strategy (COM (2020) 761) and the European Innovation Council, the private sector could be directly involved in the plan, in particular pharmaceutical companies willing to switch to non-animal methods as well as start-ups developing and perfecting them.

• **Working with Member States:** The Commission has published a plan\(^6\) to deepen the European Research Area, and select priority areas of actions with Member States. Phasing-out the use of animals should become a long-term priority action.

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**What are the benefits of phasing-out animals from scientific experiments?**

The shortcomings of animal models are well documented by the high failure rate (above 90%) of new drugs tested on animals\(^7\) and the growing number of scientific reviews indicating that they contribute little in understanding human diseases and conditions.\(^8\) By contrast, advanced non-animal models are game-changing technologies, with the potential to significantly improve our understanding of human diseases by producing data based on human biology, leading to considerable benefits for public health in terms of preventing and curing diseases.\(^9\)

There are also economic and practical benefits: transitioning to non-animal models can accelerate the pace of chemical assessments and reduce the failure rate during drug development. In addition, advanced non-animal methods represent a new, but already booming market for innovative products and services with an annual growth rate of 12% per year.\(^10\) The Action Plan would put the EU in a strong position to become a major player in this dynamic and highly promising sector.

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\(^6\)[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12960-Pact-for-research-&-innovation-in-Europe_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12960-Pact-for-research-&-innovation-in-Europe_en)

\(^7\)[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/)


