JOINT STATEMENT

Human and animal health, preservation of species and biodiversity, require the use of animals and of non-animal approaches in science

A recent European "Citizen's" Initiative (ECI), signed by 1.2 million citizens from 22 European countries and entitled "*Save cruelty-free cosmetics – committing to a Europe without animal testing*", was filed on August 31st, 2022. Unlike what its title implies, its scope extends far beyond the field of cosmetics and is massively funded by non-EU cosmetics industrial groups¹. The third part, in particular, urges the European Commission to establish a roadmap for the gradual elimination of all animal testing for scientific purposes in the EU by the end of the current mandate in July 2024.

The following signatories, on the other hand, are fully convinced that this would be detrimental for EU science, for EU strategic autonomy in medicines and vaccines, for EU jobs and competitiveness and most importantly for animal welfare globally.

The use of animals for scientific purposes has been regulated in Europe since 1986 and revised in 2010. The Directive 2010/63/EU² on the protection of animals used for scientific purposes, by far the most demanding and fit-for-purpose legislation in the world, details extensive animal welfare measures, including the 3Rs principles (Replacement – Reduction – Refinement), and already foresees the complete replacement of animal use in science when scientifically possible. We fully support the Commission's delegated powers to update the 2010 Directive and its annexes – including the upcoming extension of species referred to in Annexes III and IV.

During the past decades, our organizations have been at the forefront of the implementation of the 3Rs principles as well as the development of alternative methods to the use of animals for regulatory and research purposes. To this day, we remain fully committed to the European Parliament's call for replacement "as soon as scientifically possible and without lowering the level of protection for human health and the environment"³. We, however, jointly claim that it is not yet possible to predict when scientifically valid methods replacing animal procedures will become available. Animal research and animal-free techniques should be considered complementary rather than antagonistic methods.

A complete ban on animal research or the compulsory replacement of animals in research would have serious detrimental implications. It would not only seriously limit or prohibit much crucially important life science research in Europe but also put at risk human and animal health care as well as the preservation of certain animal species. It would pose a serious threat to the capacities of European research-performing organizations, including universities, to face upcoming sanitary crises, to improve our understanding of human and animal diseases and, based on this knowledge, to develop effective medical diagnostics and therapies, safe drugs and vaccines. Last but not least, such a ban would no doubt **trigger a brain drain and accelerate the delocalization of animal research to countries where the standards for animal welfare are lower, less stringent and less ethical than they already are in the EU.**

We, the following signatories, therefore call on European leaders to consider that:

¹ 42% out of the 2.1 million € originate from Unilever, Dove, Bodyshop and Lush Cosmetics UK

² DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes

³ European Parliament resolution of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education

- 1. The use of animals for scientific purposes is necessary to address citizen expectations that range from animal welfare and health (e.g. reduction of antibiotics and hormones use, affective states of the animals, return to the open air of animals from intensive breeding) to meat/milk/egg quality, while encompassing environmental concerns (e.g. competition between feed and food, greenhouse gas and climate change, resource efficiency, low input and organic systems) as well as implementing measures for preserving biodiversity as well as ecology of wild animals (e.g. wildlife monitoring methods within natural environments).
- 2. In the last decades, basic research, especially in cell biology and molecular biology, has allowed an unprecedented development of new research techniques in New Approach Methodologies (NAMs), including the use of stem cells to create organoids that can reflect the structure of tissues, and the use of sophisticated cell culture systems, that is to say organs on chips. Up to a point, these techniques have successfully replaced animal experiments and have initiated methods that have in many cases increased the quality of research outputs. Still, for all their worth and sophistication, such model systems are far from covering the biological complexity of the systems studied in health and disease. At the multi-systemic level many existing alternatives are not applicable e.g. cardiovascular diseases, immunology, cancer, cognition. Animal models may help us understand some of this complexity but also have their limitations, as all model systems do. Human-based model systems are becoming increasingly important, but their development is hampered by the availability of human tissues and ethical issues.
- 3. In the EU, it is estimated that 179 million Europeans live today with brain conditions, mental and neurological alike, while the cost of all brain disorders is estimated at over €800 billion per year. Understanding how the brain works remains one of mankind's greatest challenges. The brain is a complex system, determining every aspect of life, from behavior and perception to movement, sleep, memory, thoughts and feelings. The existing alternative methods are not yet sufficiently developed to allow addressing the complexity of this system.
- 4. The main funders of the ECI are asking for stricter rules to be implemented in the European Union, whereas this is not the territory in which they operate. This can be interpreted as a deliberate act of foreign interference in EU science.
- 5. EU research sovereignty must be preserved. Until recently, the supply of primates for experimentation was dependent on China. China's drastic ban on the global supply of primates for research after the outbreak of COVID-19 and airline companies' decision to forbid the transportation of such animals, together with the steady increase in the average price of research animals, pose serious threats to the progress of brain research in the EU. What is more, relying on biomedical advances developed outside the EU endangers the EU's ability to lead and further boost scientific innovation, discovery and leadership. Unless the shortage of animals for research in the EU is swiftly addressed, the EU will be dangerously dependent on China to test new treatments not only for Covid-19, but for all those currently underway regarding, among others, cardiometabolic disease and neurological disorders.
- 6. Animal welfare would paradoxically be affected too: irrespective of a complete ban on the use of animals in research at EU level, biomedical research with animals would continue elsewhere in the world, and most cases with much lower standards for animal welfare.
- 7. Communication and accountability to policymakers and society at large about the use of animal and non-animal methods have to be maintained and, when possible, further improved. Any research method, including animal experiments as well as non-animal technologies, has its own specific benefits and limitations. These have to be highlighted with a specific focus on scientific validity and ethical considerations.

In conclusion, in the current context, we strongly advise against 1) a ban on the use of animals and animal testing in research, 2) a revision of the 2010 Directive on the protection of animals used for scientific purposes, and 3) a roadmap with milestones towards full replacement of animals in research. The EU at large should instead acknowledge the necessity of using animals in research to solve major societal health and biodiversity problems and invest in the development of new techniques to further improve animal welfare, reduce the number of animals used, and refine the techniques employed for their use. Scientific research for human and animal health, for biodiversity and preservation of species, is a public good and cannot be handled in a manner akin to the management of industrial goods (e.g. cosmetics and chemicals).

Brussels, 22 May 2022

The signatories

AVIESAN

the French Alliance for Life Sciences and Health

CEA & RESEAU CHU & CNRS & FRANCE UNIVERSITES & INRAE & INRIA & INSERM & INSTITUT PASTEUR & IRD CDEFI & CIRAD & EFS & INERIS & INSTITUT CURIE & INSTITUT MINES-TELECOM & IRBA & IRSN & UNICANCER

ZonMw

the Netherlands Organization for Health Research and Development

