

## The Guild's position on the use of animals in research

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# The Guild proposes recommendations on the use of animals in research

## Introduction

On 16 September 2021, the European Parliament adopted a resolution on measures to accelerate phasing out the use of animals in research through more effective support for the development of “alternative animal-free methods” and preferential funding of research proposals that do not entail the use of animals.<sup>1</sup> While acknowledging the contributions of animal research to the improvement of human and animal health, Members of the European Parliament voiced the concern that the number of animals used in research has not significantly decreased since the entry into force of the Directive 2010/63/EU on the protection of animals used for scientific purposes.<sup>2</sup>

On 10 February 2022, the European Commission answered the European Parliament’s resolution.<sup>3</sup> It did not support the call for action

plans (with timelines, indicators and milestones) to accelerate the development of alternative animal-free methods. The Guild welcomes this position, since a phase-out of the use of animals in research disconnected to scientific progress will put health research in Europe under major threat.

## 1. Full commitment of the scientific community to the 3Rs principle

The Guild highlights that the universities and their researchers are fully committed to the implementation of the 3Rs (Replacement – Reduction – Refinement) principle. The Directive 2010/63/EU contributes to translating this principle initially developed by the scientific community<sup>4</sup> into standards for the protection of animals used for scientific purposes. Through this principle, the use of animals in research is prohibited if conclusive data can be obtained

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<sup>1</sup> 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 (2021/2784(RSP)).

<sup>2</sup> 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.

<sup>3</sup> Follow-up to the European Parliament non-legislative resolution on plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education.

<sup>4</sup> Russel, W.M.S., and Burch, R.L. (1959) *The Principles of Humane Experimental Technique*. London: Methuen & Co. Limited.

through alternative methods. If replacement is not possible, the numbers of animals used in research should be reduced and refinement of “breeding, accommodation and care, and of methods used in procedures, [must aim at] reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals” (Article 4).

The 3Rs principle already contributes effectively to the protection of animals used in research. The European Commission rightfully notes that “the EU has [...] one of the most advanced legislations in the world protecting animals still needed for scientific purposes”. In the last decades, basic research, especially in cell biology and molecular biology, has allowed an unprecedented development of new research techniques, including the use of stem cells to create organoids that can reflect the structure of tissues, and the use of sophisticated cell culture systems, so-called organs on chips. These techniques have successfully replaced many animal experiments and have introduced methods that have in many cases increased the quality of research outputs.

One example is drug screening, where robots are used to simultaneously add hundreds or even thousands of drug candidates to human cell cultures. The massive amounts of output data enable the identification of the best compounds to move the research forward. This procedure excludes compounds that have no effect or would have severe side effects; figuring this out at the cell culture stage means that many inactive or toxic compounds can be eliminated from further research.

## 2. The limitations of alternative animal-free methods

While alternative animal-free methods can help to reduce significantly the number of animals used, animals cannot be entirely replaced in many research areas yet. Cell cultures, including organoids, do not have a fully functional circulation and immune system, and cannot show behaviour and cognition. Research in life science and medicine relies on an array of different methods, which almost always include animal-free techniques, but often require the use of animals to test conclusions on living organisms. Animals are especially indispensable in fundamental biology research to investigate biological mechanisms involving the whole body, with complex communication between tissues and organs.<sup>5</sup> Moreover, the various animal-free methods already developed are not always scientifically better than animal-based methods. Their suitability for use in various different applications still requires, in some instances, further scientific discussion.<sup>6</sup>

Therefore, The Guild supports the resolution’s call for replacement “as soon as scientifically possible and without lowering the level of protection for human health and the environment”. It also endorses the European Commission’s observation that “it is not possible to predict when scientifically valid methods will become available that can replace particular animal procedures”. As long as there is no scientifically valid animal-free method, animal research and animal-free techniques should be considered complementary instead of alternative.

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<sup>5</sup> Homberg, J.R. et al. (2021) The continued need for animals to advance brain research. *Neuron*, Vol. 109(15), pp. 2363-2498. DOI:10.1016/j.neuron.2021.07.015.

<sup>6</sup> For instance, see González-Fernández, Á. et al. (2020) Non-animal-derived monoclonal antibodies are not ready to substitute current hybridoma technology. *Nature Methods*, Vol. 17, pp. 1069-1070. DOI: 10.1038/s41592-020-00977-5.

A total ban on animal research or a compulsory replacement of animals in research – without considering the reliability of technologies to replace animal research – would have serious implications. It will seriously limit or prohibit much crucially important life science – including medical and biomedical – research in Europe and ultimately put health care at risk. It would pose a serious threat to the capacities of European universities and other research-performing organizations to improve understanding of human and animal diseases and, based on this knowledge, to develop effective diagnostics and therapies, safe drugs and vaccines. Also, a ban on the use of animals in research may accelerate the delocalization of animal research to countries where the standards for animal welfare are lower than in Europe.

### 3. The Guild's recommendations on the use of animals in research

#### No hasty phasing out of animal research

The Guild strongly advises against the adoption of a ban on the use of animals in research or of a plan with deadlines for the implementation of alternative animal-free methods, i.e. for the full replacement of animals in research. Following the position of the European Commission, the European Union at large should instead acknowledge the necessity of using animals in research to solve major societal health 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. Nevertheless, The Guild warns against any further reduction in the funding for animal research, as any such decision would put at risk Europe's scientific development and technological competitiveness and ultimately have negative consequences on human and animal health in Europe.

#### The need for fit-for-purpose rules on the use of animals in research

The regulations on the protection of animals used for research purposes define a high standard in animal welfare in Europe. However, The Guild urges the European Commission to ensure that the current rules (especially Article 44 on the amendment, renewal and withdrawal of a project authorization) are fit for purpose and coherently implemented and interpreted across the EU member states. The Guild advocates against new (EU, national or institutional) rules that might impose additional administrative burdens on researchers and, for instance, unnecessarily lengthen the time needed to obtain authorizations for the use of animals in research. It is also of crucial importance to ensure that researchers can easily bring changes to authorized experiments when these changes could improve the welfare and health of the animals used.

The Guild highlights that skilled and adequately funded competent authorities are key for the implementation of the Directive 2010/63/EU and the protection of animals used in research. Any shortage in terms of resources (expertise, funding or infrastructures) will affect the time required to obtain authorization and the quality and consistency of the authorization process. Therefore, The Guild urges the European Commission and the EU member states to ensure that competent authorities have the expertise, financial resources and infrastructure necessary to perform their missions in accordance with the highest standard for animal protection and research quality and consistency across Europe.

#### Maintained engagement of the scientific community in the implementation of the 3Rs principle

Reducing the number of animals used in research and protecting animal welfare rely

extensively on researchers and their awareness that animal research can benefit humans only if it is conducted in accordance with the highest scientific and professional standards and good laboratory practices. The Guild recommends a close engagement of the whole research community in the implementation of the 3Rs principles. It is particularly important to acknowledge and encourage the efforts made by researchers to protect animals used in research and improve their welfare. The Resolution of the European Parliament urges those involved to “prioritise actions to educate, train and retrain scientists, researchers and technicians” in order to accelerate the uptake of alternative animal-free methods, reduce the number of animals used in research, and refine research procedures, and The Guild fully supports this. It is also important that these education and training initiatives include awareness-raising actions within universities and research-performing organizations and that they are organized not only top-down but also bottom-up.

## Communication and transparency on animal research

Communication and transparency on the use of animals in research are critical. It is important to remind policymakers and the general public that animal research has been at the foundation of all major breakthroughs in medical research not only in the past. For instance, immunotherapy, which has revolutionized the treatment of cancer, and as a more recent example, the COVID-19 vaccines could not have been developed without animal research. The Guild acknowledges the efforts of the European Union to collect and publish data on the use of animals in research.<sup>7</sup> It also encourages the sharing of knowledge (to support the implementation of the 3Rs principle) and transparency-raising initiatives such as transparency agreements, whereby the biomedical research sector commits to openness and transparency as well as public engagement for a greater understanding of the rationales for using animals in research.<sup>8</sup>

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<sup>7</sup> ALURES statistical database: [https://ec.europa.eu/environment/chemicals/lab\\_animals/alures\\_en.htm](https://ec.europa.eu/environment/chemicals/lab_animals/alures_en.htm)

<sup>8</sup> Transparency Agreements in Europe: <https://www.eara.eu/transparency-agreements>



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