

## **European Brain Council Statement on the Use of Animals in Scientific Research**

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A recent European Citizens' Initiative (ECI), 'Save cruelty free cosmetics – Commit to a Europe without animal testing', calls for the 'phasing out of the use of animals in science' and urges the European Commission (EC) to '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 brain community would like to moderate these demands: a complete ban of the use of animals in biomedical research is premature. Although considerable progress has been made using alternatives, most of what can be learned about the brain and behaviour still depends directly, or indirectly, on research in animal models. In its response to the European Parliament Resolution on 'Plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education', the EC also acknowledges that despite biomedical advances, alternative methods still have very limited uses and that it is still not possible to predict when such methods will become available. Thus, in the absence of scientifically valid methods that can replace particular animal procedures, phasing out the use of animals in medical research would have major consequences and impact the quest to improve the quality of life of the many citizens affected by brain conditions, neurological and mental alike.

In the EU, it is estimated that 179 million Europeans are living with brain conditions, mental and neurological alike. The cost of all brain disorders is estimated at over €800 billion per year — a figure that is on a steady rise and excludes the growing impact on the lives of caregivers, who play a vital, often debilitating, role.

### **The brain is a vital and complex organ**

Understanding how the brain works remains one of humanity's greatest challenges. The brain is a complex system, determining every aspect of life, from behaviour 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.

### **Animal research is essential for the development of scientific knowledge**

Research using animal models has been essential for the advancement of scientific knowledge and understanding how the brain works:

- A large number of diseases have benefitted from such research, including – inter alia - cancer, cardiometabolic disease, rare diseases, neurological and neurodegenerative diseases. It has helped society understand the functioning of organisms and develop fundamental treatments and medicines for human and veterinary use, such as anaesthetics, antibiotics, vaccines, etc.

- The ultrafast development of vaccines and antiviral drugs during the COVID-19 pandemic would not have been possible without prior animal studies paving the way. Many of the drugs used in chemotherapy were developed through animal testing, including tests on mice and rats.
- The development of pacemakers was also aided by animal testing, including studies on dogs to determine the safety and effectiveness of the devices. Various animals have been used in dental implant research, including dogs and pigs because their tooth structure is similar to that of humans.
- Animal research has also been essential for the development of medical equipment that allows for minimally invasive surgery and imaging, such as MRI. Early models in machine learning and AI were directly based on insights on visual coding in mammalian cortex, and algorithmic insights into how neural circuits work continue to serve point of comparison for anything related to artificial intelligence.
- What is more, it is necessary to evaluate the toxicity, safety and efficacy of drugs, vaccines and other products intended for humans, as well as for companion animals and those used in animal husbandry. As an example, thalidomide is a drug that was not tested in animal embryos and led to a disaster.

### **Looking at CNS-modifying drugs**

Despite advances having been made in neuroscience research in the past decades, disease-modifying drugs for central nervous system (CNS) disorders (including neurodegenerative disorders) are still lacking. One of the main bottlenecks sustaining this limitation is the need to develop animal models better mimicking these disorders. Due to the well-known complexity of the brain, this gap can only be addressed by conducting neuroscience research in experimental animals.

Animal experimentation should therefore remain a backbone for the development of new disease-modifying drugs targeting the CNS. These approaches cannot be implemented at the in vitro model and there still is a very long race for pushing forward the development of reliable alternatives. The chances of replacing animal experimentation for CNS disorders with in vitro are unlikely to succeed, keeping in mind that the inherent complexity of the brain dictates the use of in vivo animal models at the system neuroscience level, these models providing the adequate context for testing new therapeutics.

### **Animal research is one of the most regulated and supervised scientific activities**

All EU researchers must comply with regional, national and European legislation that delimits and controls what can and cannot be done. In research centres, ethics committees are charged with evaluating applications to use experimental animals and, ultimately the competent national authority either grants or rejects the use of animals in experiments. The competent authority supervises the safeguarding of animal welfare and compliance with the authorised procedures, sanctioning those who violate the regulations in force.

Any person caring for or using animals for experimentation must be trained and qualified to perform their tasks, operating only under supervision. Training must be carried out – according to legislation – continuously and updated regularly, always under the control of the competent authority.

### **Replacement, Reduction and Refinement**

In-vitro experimentation is undertaken before resorting to animal models. Experimental animals are only used in scientific research or higher education when there are no alternative methods available. The current legislation demands that most advanced methods are always used to minimise harm or pain to the animals and promote their welfare.



The development of alternative methods is promoted at all times in order to replace the use of animals while maintaining the necessary scientific rigour.

### **Preserving EU research sovereignty**

Until recently, the supply of primates for experimentation has been dependent on China. China's drastic ban of the global supply of primates for research after the outbreak of COVID-19 and airlines companies' decision to ban transportation of such animals, the dwindling number of animals used in research in the EU and the rocketing average price of research animals spurred by desperate demand pose serious threats to the progress of brain research in the EU.

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 in development for cardiometabolic disease, cancers, neurological disorders. The EU would increasingly depend on others for biomedical innovation and miss its European research goals to create jobs and retain leading scientists, boosts economic growth, promote industrial competitiveness and optimise investment impact within a strengthened European Research Area.

Animal welfare would paradoxically be affected too: irrespective of a complete ban on the use of animals in research at the EU level, biomedical research with animals would continue across the globe, in some cases under conditions with much lower standards for animal welfare.

### **The problem of setting a deadline for phasing out animal experiments in the EU**

The ECI calls for a fixed deadline for phasing out animal experiments in the EU. This is most arbitrary and unrealistic: The EU directive in force already includes the gradual reduction of animal experiments as soon as this is scientifically possible. It is not possible to politically dictate what can be scientifically possible by a certain point in time. The EC thus will need to come with clear guidance on what such a phase-out plan might look like and how a target date and possible milestones could be sensibly formulated.

**At present, the EU is confronted with a high number of unmet needs for people with brain conditions.**

**The EU citizens' mental health is affected by the consequences of the COVID-19 pandemic and a disturbed geo-political environment.**

**We cannot exclude scientific research on brain disorders and its resulting innovation, for the sake of those who will benefit from it, their families and society at large.**

**Let's avoid devastating measures that would affect the EU's research, innovation, and competitiveness and, ultimately, the European population as a whole.**

**Let's encourage scientific advancement while offering scientists the time and means to develop viable alternatives.**

