

European Directive 2010/63/EU

– FAQs



Why is animal research important?

Animals are required to further our understanding of how the bodies of humans and animals work, how diseases affect them, and how diseases can be prevented or treated. Almost every major breakthrough in human and veterinary medicine has depended on the use of animals at some stage in the research, development or testing of new therapies.

The majority of veterinary medicines are developed from medicines developed for humans. Worldwide, research using animals is a legal requirement prior to conducting clinical trials of a new medicine in humans.

What is European Directive 2010/63/EU?

The Directive is the recently revised EU legislation that regulates the use of animals in scientific research. Updating and strengthening its predecessor directive on animals in research (86/609/EEC), the Directive was adopted in 2010 after a rigorous process of debate and negotiation with a wide range of interested parties, and came into full effect in 2013. The Directive will be reviewed in 2017 as part of the EU's normal legislative review process.

The Directive provides for the most progressive and stringent framework worldwide for the protection of animals used in scientific research. It harmonises regulation across the EU so as to promote both animal welfare and high-quality scientific research. It requires an independent harm-benefit analysis to

determine whether any licence to use animals in research is justified and will be awarded. It places an explicit obligation on licensed researchers to adopt the '3Rs':

- Reduction – using fewer animals to achieve the same scientific goals.
- Refinement – optimising the welfare of those animals that are used.
- Replacement – using scientifically valid non-animal alternatives where they are available.

Beating brain diseases

Brain diseases in Europe are an enormous social and economic burden. They are the largest contributor to morbidity,¹ costing around 800 billion euros² each year.¹ It is estimated that around 179 million people suffer from a brain disease in the EU,¹ and with an ageing population this number is set to increase significantly. Developing strategies for improved prevention and treatment will continue to necessitate the use of animals in research. For example, advances in our understanding that enabled scientists to develop immunisation therapy for Alzheimer's disease were made possible through research on vervet monkeys that were developing cerebral amyloid beta plaques, involved in causing Alzheimer's, similarly to humans.³

Are animals too different from people for animal models of disease to be valid?

While there are clearly differences between animals and people, the biology of humans and other animals, particularly mammals, is remarkably similar. We have the same organs, controlled by the same (or very similar) nerves and hormones, as other mammals. Where there are substantive differences, these are taken into account by researchers and can actually help to further scientific understanding of a particular problem. Many animals suffer naturally from the same diseases as humans, and can be used to study those diseases. In other cases, researchers can use an 'animal model' of a disease that is close to the human condition. The similarity in the biology of humans and animals means that nearly 90 per cent of the veterinary medicines that are used to treat animals are the same as, or very similar to, those developed to treat humans.

What about scientific research that isn't for a medical application?

Many of the advances of modern medicine would not have been possible without research using animals. Although not intended to have a direct medical application, there are many instances where basic biomedical research has led to significant medical advancements. For example, the discovery of place cells – the brain cells that provide us with a cognitive map of our environment – would not have been possible without having been able to study these cells in rodents. Now, several years after John O'Keefe's original discovery (for which he recently won a Nobel Prize), it is widely recognised that this system of place cells is affected in people with dementia and Alzheimer's disease. Understanding how spatial memory works gives researchers developing treatments for brain disorders a huge helping hand.

Scientific research assessing the effects of changes in the environment impacting on our wildlife is becoming increasingly important as the pace of environmental change increases. An example of this type of research would be blood sampling to assess new patterns of disease exposure in a particular species.

What is being done to reduce and refine the use of animals and introduce alternatives?

The scientific research community is best placed to develop alternatives to animal models and is committed to doing so. New approaches, such as tissue engineering, stem cell technologies and computer modelling, show promise for replacing the use of animals in some areas of research. All such alternative methods require formal validation to demonstrate that they are at least as reliable as equivalent research using animals. The European Centre for the Validation of Alternative Methods was established in 1991 and the Directive has placed further duties on it, including establishing the European Union Reference Laboratory for Alternatives to Animal Testing. Since 1991, the Centre has validated over 30 alternative methods, around 80 per cent of which have been accepted by

regulatory agencies at an international level.⁴ National support is important too; in the UK, for example, the discovery and application of new technologies and approaches is supported by the National Centre for the Replacement, Refinement and Reduction of Animals in Research.

The Directive also places a legal duty on the scientific research community across Europe to use the most appropriate number of animals necessary in each study. However, reduction and refinement will not always lead to an overall reduction in the number of animals used. This may be because greater numbers of species with lower sentience, such as rodents and fish, are being used to replace animals with higher sentience, such as monkeys and dogs. Also, where the overall volume of biomedical research being conducted in the EU increases to address major remaining health problems, the overall numbers of animals used in research may not decrease even though the 3Rs have been deployed rigorously.

Will animal use in research be required in the future?

Non-animal research methods are able to provide researchers with information about individual parts of the body but do not yet fully replicate the intricacy of the entire human body and how different parts of the body interact. The complexities of how a new medicine may affect the circulatory system, the safety and efficacy of new stem cell therapies for diabetes or stroke, and the side-effects of vitally needed new antibiotics are all examples of research questions that cannot currently be answered without research using animals. Moreover, veterinary and environmental research on wildlife will always necessitate research on animals.

Animal research therefore remains a small but essential and integral part of the research that underpins all bioscientific knowledge and it continues to be vital in the advancement of knowledge and the development of new treatments for humans and animals alike. We support the use of animals in research when the potential health benefits are compelling and where acceptable ethical standards can be met and there are no suitable alternatives..

Find out more about research in Europe involving animals:
wellcome.ac.uk/euanimals

References

¹ Wittchen HU et al. The size and burden of mental disorders and other disorders of the brain in Europe 2010. *Eur Neuropsychopharmacol* 2011;21(9):655-79.

² DiLuca M, Olesen J. The cost of brain diseases: a burden or a challenge? *Neuron* 2014;82(6):1205-8.

³ Lemere CA et al. Alzheimer's disease abeta vaccine reduces central nervous system abeta levels in a non-human primate, the Caribbean vervet. *Am J Pathol* 2004;165(1):283-97.

⁴ <http://eurogroupforanimals.org/what-we-do/category/animal-testing/alternative-methods>