

# The reality of research with animal models in Spain – COSCE statement

The Confederation of Scientific Societies of Spain (COSCE) through its Commission for the Study of the Use of Animals in Scientific Research has issued a statement to clarify the reality of research with animal models in Spain, and the need for their use for the advancement of science.

## Translation from Spanish

IN recent months, several news items have been published regarding animal research from which it could be understood that it is possible to dispense with these practices in biomedical research. At the same time, we believe that these publications stigmatise researchers and all professionals in charge of the care and welfare of these animals, who, as a whole, carry out their activities honestly and responsibly.

Through this statement we want to show that this message transmitted does not correspond to the existing reality in our country.

Research with animal models is essential for the advancement of scientific knowledge.

Animal research has helped to understand the functioning of organisms, and to develop fundamental treatments and medicines for human and veterinary use that we use today.

For example, anesthetics, antibiotics, and vaccines such as covid-19, without forgetting vaccines against polio, tetanus and papillomavirus. In addition, we owe to animal research the development of therapies against cancer, neurodegenerative diseases and rare diseases. Animal research has also been basic for the development of medical equipment that allows minimally invasive surgery, and fundamental imaging methods such as magnetic resonance.

Almost all Nobel laureates in Physiology or Medicine have used animals in their pioneering research.

Animal research is still necessary to evaluate the toxicity, safety and efficacy of drugs, vaccines and other products intended for humans, but also for companion animals and those used in livestock. Animal research is



also one of the most strictly regulated and supervised scientific activities.

All researchers in Spain must comply with regional, national and European legislation that defines and controls what can and cannot be done. In research centres, ethics committees are responsible for evaluating applications to use experimental animals and ultimately the competent authority, in our country in the autonomous communities, is the one who authorises, or not, the use of these animals in experiments. Additionally, the competent authority is also in charge of supervising compliance with authorised procedures and safeguarding animal welfare, as well as sanctioning those persons or institutions that, after being investigated, are found to have violated current regulations.

Any person who cares for or uses animals for research, must be trained and qualified to perform any of these functions: animal care, euthanasia, performance and design of procedures, responsible for animal welfare and designated veterinarian. This is carried out through specific training modules, and after a period of supervision. The training must be carried out continuously and updated from time to time, according to the legislation and always under the control of the competent authority.

The principles that govern experimentation with respect to animal welfare are: Replacement, Reduction and Refinement (the 3Rs) of care and use procedures. Research animals are only used in scientific research, or higher education, when there are no alternative methods to avoid the use of animals.

In fact, between 2009 and 2020, the period for which we have official data from the Ministry of Agriculture, Fisheries and Food (MAPA), there has been a 46% decrease in the use of animals. Overall, the smallest number of animals compatible with obtaining conclusive results is used. And the most advanced methods are always used to minimise any damage or pain to the animals, promoting their well-being.

Generally, before reaching animal experimentation, there is a great deal of preliminary work on *in vitro* research, fundamental in basic research and from which, for example, it is possible to continue with animal trials with those drug candidates that have shown promising results in the previous phases.

At all times, the development of alternative methods is promoted in order to replace the use of animals and at the same time maintain the necessary scientific rigour. At European level, there is the European Reference Center for the Validation of Alternative Methods (ECVAM).

Alternative methods are getting better and better, but they still cannot fully replace animals.

The use of animals for basic scientific research accounts for approximately 80% of the uses of animals in our country, according to the figures published annually by the MAPA. The remaining 20% corresponds to the so-called regulated or regulatory research - the use of animals is mandatory in the preclinical development phases of medicines, to evaluate their safety and efficacy, prior to their use in the target species, be it humans or other animals.

Animal studies are also required for consumer chemicals to assess their safety for man, animals and the environment.

These uses are typified and standardised and are required by the different regulatory agencies in order to finally approve medicines, vaccines or other products intended for humans or other animals.

All medicines and vaccines must be previously validated in animals (in one or several species, depending on the case), also complying with strict regulations (GLPs or Good Laboratory Practices), to establish their safety and efficacy, before they can be evaluated in people, through the well-known clinical trials with their different phases (I, II, III and IV).

In September 2016, COSCE launched the agreement for transparency in animal experimentation to promote knowledge of why, where, for what, when and how many animals are used in research in our research centres. This agreement, contains four commitments that seek to clearly communicate to all citizens the reasons why research animals continue to be used, and has already been adhered to by 153 institutions throughout the country. These include universities, research centres, scientific societies, companies in the sector, patient associations, hospitals, science parks and public research bodies. This Spanish agreement promoted by COSCE includes a greater number of national institutions of all the transparency agreements already launched throughout the world.

We firmly believe that only from the rigorous and truthful information on animal research, which we must and want to provide to citizens, will we be able to advance in the normalisation of this scientific activity, which has allowed us today to have safe medicines, vaccines and treatments that are effective for all.

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