

Ethics in animal experimentation

Introduction

In the 1970s, under pressure from a section of society and on the initiative of groups of researchers, committees for the improvement of conditions for the use of laboratory animals were set up, first in North America and then in Europe. In this way, an ethical approach to animal experimentation was born and has been constantly adapted to scientific progress. Complementing the regulations that lay down the legal conditions for experimentation and aim to curb abuses, the ethical approach, dominated by the notion of the animal as a sentient being, endeavours to provide the experimenter with the principles of respect and avoidance of animal suffering. Before any experimentation is carried out, it should receive the opinion of an Ethics Committee, which is internal in the case of private establishments and regional in the case of public establishments.

Faced with these inevitable shortcomings, in the 1970s the scientific community took the initiative of adopting resolutions setting out the rules of conduct considered to be moral, which every experimenter should apply. This set of rules, regularly revised and adapted, represents the translation of ethical conduct in animal experimentation.

1. Regulations on the protection of experimental animals

- **European bodies:**

The Council of Europe :

The European Convention for the Protection of Vertebrate Animals used for **Experimental and other Scientific Purposes (31 May 1985)**.

Signed by France on 2 September 1987, it has been in force since 1 December 2000.

Appendix A, revised on 15 June 2006, sets out guidelines for the housing and care of animals.

Directive 86-609/EEC of the Council of the **European Communities** of 28 November 1986 on the **protection of animals used for experimental and other scientific purposes**.

Amended by Directive 2003-65/EC of 22 July 2003, it is currently being revised.

- **French regulations:**

Decree 87-848 of 19 October 1987: relating to experiments on animals; it was amended by Decree no. 2001-464 of 29 May 2001 and by Decree no. 2007-409 of 23 March 2007 publishing the Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, signed in Strasbourg on 22 June 1998.

2. Ethics of animal experimentation in biomedical research

The first European text on the protection of animals used for experimental purposes appeared in 1985. This was the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, supplemented by a technical annex dealing with guidelines for the accommodation and care of animals (ETS 123 and Annex A) [2]. This Convention was followed by EEC Directive 86-609 and Annexes I and II [3], which set out the guidelines to be followed by member countries when translating it into national law.

In France, this directive was translated into French law by decree no. 87-848 of 19 October 1987 [4relating to experiments on animals and its three implementing decrees of 19 April 1988 [5]. The first lays down the conditions for supplying animals to approved laboratories, the second sets out the conditions for granting authorisation to experiment on animals and the third defines the conditions for approving, fitting out and operating animal experimentation establishments.

These texts on the protection of laboratory animals will be supplemented by Decree No. 2001-464 of 29 May 2001 [6which clearly defines the different fields of action of animal experimentation. These regulations cover the approval of premises where experiments are carried out, give researchers a sense of responsibility by authorising them to carry out experiments, and regulate the conditions under which painful experiments may be carried out by requiring anaesthesia whenever necessary. The penalties for breaches of these provisions are specified.

Any person required to take part in experiments or in the care of animals must first have received specific training to enable them to understand the physiological and behavioural needs of the species used, and must be able to assess the most appropriate conditions for the animal's well-being.

The guidelines for the housing and care of animals set out in Directive 86-609 set out the conditions for the design and operation of experimental establishments, and enable the animal's environment to be standardised as far as possible.

Since then, Appendix A of the Convention has been revised, published in June 2006 and applied from June 2007. The groups of experts specialising in the various fields who contributed to the drafting of this document provided comprehensive information on the facilities, environment, enrichment, care, transport and handling of all the species used, based on developments in knowledge and practices since 1986.

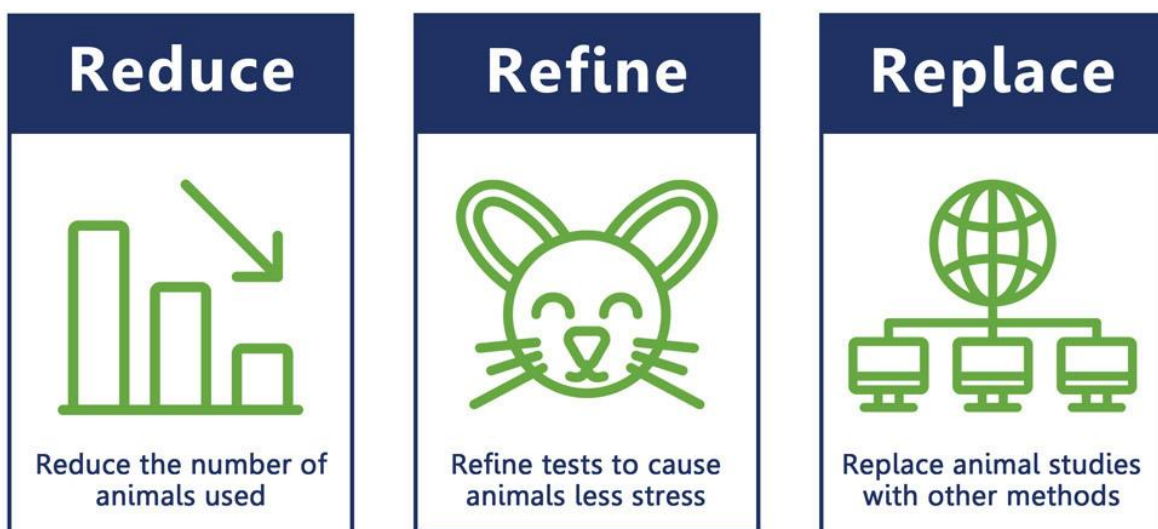
For over 20 years, animal experimentation has evolved within a well-defined framework, the aim of which is to prevent the mistreatment and abuse of laboratory animals.

3. The main principles of ethics in animal experimentation

This ongoing quest can be summed up in a simple rule known as the "3Rs", which we owe to two researchers, W. Russell and R. Burch . In 1959, in "*The principles of Human Experimental Techniques*", they published recommendations that were forgotten until the end of the 1970s:

- *Replacement*" for substitution, - *Reduction*" for reduction (in the number of animals), - *Refinement*" for optimisation.

The 3 R's of Animal Research



These three recommendations are considered so important by English-speaking authors that they are often confused under the term '*alternative methods*'.

They will be developed in the contributions that follow.

A fourth R could be added, "*Respect*" for respect or consideration (for the animal). It would reinforce the meaning of the ethical approach to animal experimentation.

As the ethics committees were set up, the principles of ethics in animal experimentation were the subject of the publication of Charters such as the "Grice Charter" or the "Charter for an Ethical Approach to Animal Experimentation" of the regional committees. This set of rules, to which researchers adhere, complements older charters

4. Progressive introduction and formalisation of ethics committees

As animal experimentation is recognised as necessary in the current state of our knowledge, the main fundamental principles described in the charters recommend limiting the use of animals to what is strictly necessary and recommend preserving their welfare as much as possible:

- Preventing unnecessary suffering.
- Maintenance of the experimenter's qualifications and skills.
- Assume responsibility and justify the research process you are embarking on.
- Use of ethics committees to evaluate protocols and guarantee the legitimacy of the scientific approach undertaken.

The main role of an ethics committee is therefore to examine a priori all study protocols that require the use of laboratory animals.

This assessment will focus on the justification for the study to be undertaken, the model chosen and the number of animals required. The techniques and methods involved will be discussed. The degree of suffering suffered by the animal should be estimated before the experiment and the methods for alleviating it documented. Finally, if the animal is to be killed, the euthanasia methods will be described.

The remit of an ethics committee can go beyond the ethical assessment of protocols to include monitoring and maintaining the skills of experimenters.

The ethics committee is also a unique forum for the exchange and collection of good scientific practice and a channel for disseminating this know-how, a factor for progress in the experimental approach.

Conclusion

In the field of animal experimentation, at both national and international level, the founding texts on the protection of laboratory animals largely preceded the introduction of ethical assessment. This approach, strongly influenced by the philosophical and religious contexts of the preceding centuries, has had great difficulty in gaining acceptance, but all the regulatory and ethical provisions are now in place and have enabled major advances to be made. Scientists have become aware of the need to conduct animal trials under the best possible experimental conditions and appreciate the support of ethics committees in this shared reflection. Experimental designs and results have improved considerably as a result. In vitro techniques, which have been widely deployed thanks to the technological advances from which they have benefited, have made it possible to use animals only later in the research process, thereby greatly reducing the number of animals used.

Thanks to the recent creation in France of the Comité national de réflexion éthique (National Committee for Ethical Reflection), which should very quickly facilitate dialogue and communication between public and private research ethics committees, animal protectors, philosophers and lawyers, the debate will broaden and go even further to prepare the future of animal experimentation.