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Reduce, Refine, Replace

The European Union has passed new laws for the protection of laboratory animals according to the 'three Rs' concept.

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After 2 years of negotiations, debates and delays, September 2010 saw the European Parliament approve new legislation for the protection of laboratory animals. Member states have 2 years to implement the new rules. The existing animal-welfare legislation, dating back to 1986, was considered outdated, open to interpretation and political rather than regulatory in nature. In addition, measures were needed to close the gap in standards as member states passed their own laws on lab animal protection. The objectives of the new directive are to improve the welfare of animals used in scientific procedures while ensuring fair competition for industry and fostering research of the highest quality.

Among the key provisions, all experiments are to be ethically assessed and preauthorized; minimum housing and care requirements are set; and alternative methods recognized by the European Community are to be used instead of animal testing wherever possible, and the development of such alternative methods is strongly encouraged. The directive strongly implements the 'three Rs' concept: reduce the number of animals; refine techniques to lessen pain and discomfort; and replace animal studies with alternatives. National governments will enforce the proper application of these provisions by regular inspection of breeders, suppliers and users of research animals. To promote transparency, some of these inspections will be unannounced.

The new legislation completely bans the use of great apes for scientific experiments, but member states can be granted exceptions in emergency situations, such as unexpected outbreaks of life-threatening diseases. Other nonhuman primates, such as macaques, can still be used for basic and biomedical research in relation to potentially life-threatening or debilitating conditions such as AIDS and Alzheimer's disease.

The reactions of the pharmaceutical industry to the new law were positive, as they had feared much more restrictive measures. Animal-protection groups gave the new directive a mixed welcome, expressing various concerns. Among those is the fact that the new law will prevent member states from adopting stricter rules at a national level. The biggest disappointment for them is the lack of a clear commitment and long-term targeted strategy to reduce and replace animal experiments. Animal-welfare organizations were also aiming for tighter rules on the use of nonhuman primates (other than the symbolic exclusion of experimentation on great apes, which are not used at present in laboratories of the European Union) and a ban on experiments involving what is classified as severe and prolonged suffering. However, they acknowledge the progress made and see this as the beginning of a process leading to further improvements in animal welfare.

The original draft proposed in November 2008 aimed to limit the reuse of animals if a test involved more than what is considered 'mild' pain. That and other restrictions proposed in the draft alarmed both academic researchers and the pharmaceutical industry. In May 2009, bioscience organizations in the UK, including the Wellcome Trust, the Medical Research Council, patients and medical groups, issued a "declaration of concern." They pointed out that too strict a control on animal experimentation could drive animal research to countries with lower standards for animal rights, in addition to hindering bioscience by increasing costs and administrative burdens. Research organizations from across Europe were also worried that a 'mild' pain limit could in fact result in the use of even more animals. Strong lobbying by the bioscience industry led to changes in the draft legislation to allow reuse of animals after experiments involving 'moderate' pain.

The resulting legislation is considered by most—including members of the European Parliament, researchers and animal-protection groups—as a balanced package that increases protection of animals in the laboratory, encourages the development of alternative methods and ensures that medical research and expertise stays in Europe. The directive sets up the highest standard in animal protection in the world and hopefully will serve as an example for other countries.

Some legislative changes are expected in the USA as well. In August 2010, the Great Ape Protection Act was introduced in the Senate (GAPA; S. 3694), a companion to the May 2009 version from the House of Representatives (H.R. 1326), which aims to prohibit invasive research on great apes and promote the retirement of federally owned animals to sanctuaries. The USA is the only developed country in the world that continues large-scale confinement of chimpanzees, with approximately 1,000 animals still living in US laboratories, half of them federally owned. The ban would include any research involving the restraint, tranquilization or removal of animals from their social group, as well as tissue sampling.

The American Association for the Advancement of Science, FASEB and other scientific organization oppose the act, pointing to the negative effect of such restrictions on medical research. After being bred for use in research into human immunodeficiency virus, but failing as an effective model, chimps have been used for other viral studies, and they now represent the only existing animal model of hepatitis C. However, practical restrictions do arise from the high cost of meeting the behavioral, environmental and social needs of great apes in a laboratory environment. This limits the number of animals included in the experimental design in most labs, which in turn puts restrictions on data interpretation. These practical issues, as well as the ethical issues, should be considered in debates on the future of great-ape research in the USA.

Ethical concerns for animal welfare are often at odds with the advancement of basic science and the development of new therapies for human disease. Efforts to find alternative technologies aimed at replacing animal testing should be promoted wherever possible by funding organizations and the scientific community. Laws and regulation should be updated frequently to reflect the greater understanding of animal behavior, awareness and ability to experience pain. The European Parliament intends to review its animal protection legislation much more frequently in the future. It would be prudent for other nations to follow suit.