LETTERS

Current Brazilian Law on Animal Experimentation

Last year, *Science* published a story on the Brazilian scientific community's battle against a series of local attempts to ban laboratory animal experimentation and the hope for a federal law addressing laboratory animal research that would put a stop to such local bans ([1](#)). The Brazilian Federal Law on Animal Experimentation (Law 11794) was enacted on 8 October 2008.

Law 11794 establishes procedures for the scientific use of animals and abrogates the previous Law 6638/1979, which was ineffective because it was not regulated by the Brazilian Executive Power. Without regulation, many issues remained ill-defined, including operational procedures and responsibilities such as licensing, accreditation, and institutional compliance inspection. The new law states that scientific research activities include basic and applied science, technological development, production and quality control of drugs and medications, food, immunobiological agents, and instruments tested on animals. The law does not extend to the procedures applied to animal experimentation in the course of veterinary, agricultural, or laboratory animal husbandry practices and procedures for the identification of animals for scientific purposes, should they cause no lasting harm.

Only universities and biomedical technical schools are entitled to use laboratory animals in teaching. The term "biomedical" is not defined within the text of the Law, which may generate difficulties given that it does not have a specific meaning in the context of education. Law 11794 does not indicate whether animal experimentation is allowed by students under 18 years old, unlike Law 6638/1979.

Law 11794 establishes The National Animal Experimentation Control Board (CONCEA), under the presidency of the Ministry of Science and Technology (MCT). Law 11794 does not clearly specify in which ministry CONCEA, as a public administrative unit, belongs. That is, there is no legal disposition tying CONCEA to the MCT. This means that CONCEA will have difficulties implementing its norms, procedures, and resolutions due to lack of ministerial power.

Only institutions accredited by CONCEA can breed or use laboratory animals for teaching and research. CONCEA is primarily an advisory body, and its powers are limited. CONCEA accreditation requires the previous establishment of an ethics committee on the use of animals (CEUA) by the license-seeking institution. CEUA is the body formally responsible for the care and use of research and teaching animals within the institution. All proposals involving laboratory animals have to be submitted and reviewed by CEUA, which has the authority to halt any teaching or research practice that does not comply with the legislation. CEUA must ensure that the facility standards and the care of animals are in accordance with CONCEA resolutions. The Committee is composed of veterinarians and biologists, professors and researchers of a specific area, and one representative of a legally established Animal Science...
Protection Society within the country. The number of members is left open with exception of the mandatory Animal Protection Society member. Considering the heterogeneous geographical distributions of researchers within the Brazilian Territory, a large variability in the number and profile of CEUA members among institutions is expected, which is problematic.

It is CEUA’s duty to keep an institutional database of researchers and procedures that use laboratory animals in research and teaching and to report the data to CONCEA. Law 11794 does not mention whether the information retrieved by CONCEA will be made available to the public. The value of public access to information has been stressed by the Federal Constitution (Article 5, XXXIII). Accountability and transparency in animal experimentation are practices yet to be learned by Brazilian research institutions and governmental bodies. The changing process will demand from CONCEA and CEUA communication skills far above those previously required.

Law 11794 places less emphasis on alternatives to animal experimentation than was previously treated legislatively and is expected by the Animal Protection Societies. A requirement that animal experimentation projects must demonstrate the relevance of their results for the progress of science and show that alternative, equally effective methods do not exist was also deleted from one of the substitutive bills proposed.

For Brazilian scientists, Law 11794 undoubtedly represents improvement. It can also support the democratic process of closing the gap between science and society. Nevertheless, its limits and potentialities will depend on the regulatory process in progress. The challenging issues that were left open by Law 11794 may lead to subjective interpretation of its content. In addition, the adoption of research practices that take into account animal welfare will depend on a government long-term action plan regarding the many and complex aspects related to human resources, training and education on animal care, management and housing, animal research facilities, replacement techniques on animal experimentation, and communication and information systems.

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