



RESEARCH

The knowledge of bioethics and Law 11,794/2008 in undergraduate courses

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Abstract

Used for education and research, laboratory animals require special care on their handling. Brazilian Law 11,794/2008 establishes the legal parameters for animal manipulation and welfare. It was accompanied by the obligatory installation of the Institutional Ethics Committees on the Use of Animals and the creation of the National Council for Animal Experimentation Control. There have been advances in the field of animal bioethics legislation. However, considering the behavior of those who handle the animals in laboratory environment, especially undergraduate students, these advances are insufficient: the information does not reach them and their attitudes remain in need of ethical reflection. This article seeks to investigate the current bioethical knowledge of undergraduate students and teachers in order to stimulate changes in conduct.

Keywords: Ethics. Bioethics. Animal experimentation. Animals, laboratory. Animal use alternatives. Animal care committees.

Resumo

Conhecimento sobre a bioética e a Lei 11.794/2008 na graduação

O uso de animais para fins didáticos e de pesquisa requer cuidados específicos. Atualmente, vigora no Brasil a Lei 11.794/2008, que rege parâmetros legais de manejo e conduta neste caso. Esta lei foi acompanhada da instalação ou adequação de comissões de ética em instituições que utilizam animais para ensino e investigação, bem como da criação do Conselho Nacional de Controle de Experimentação Animal. No entanto, apesar dos avanços, especialmente na legislação, ainda não foi consolidada nenhuma grande mudança de comportamento de pesquisadores e alunos de graduação que manuseiam animais em laboratório. A divulgação de informações deixa a desejar, e a prática acaba por repercutir a carência de reflexão ética. Este artigo busca averiguar o atual conhecimento bioético de alunos de graduação e professores com o objetivo de estimular mudanças de conduta.

Palavras-chave: Ética. Bioética. Experimentação animal. Animais de laboratório. Alternativas ao uso de animais. Comitês de cuidado animal.

Resumen

Conocimiento sobre bioética y la Ley 11.794/2008 en el grado

El uso de animales con fines didácticos y de investigación requiere cuidados específicos. Actualmente, rige en Brasil la Ley 11.794/2008 que regula los parámetros legales de manejo y conducta en estos casos. Esta ley estuvo acompañada de la instalación o adecuación de comisiones de ética en instituciones que utilizan animales para enseñanza e investigación, así como de la creación del Consejo Nacional de Control de Experimentación Animal. No obstante, a pesar de los avances, especialmente en la legislación, aún no se ha consolidado ninguna gran transformación en el comportamiento de los investigadores y alumnos que manipulan animales en el laboratorio. La divulgación de informaciones es insuficiente, y la práctica acaba reflejando la falta de reflexión ética. Este artículo procura identificar el conocimiento bioético actual de los alumnos de grado y de los profesores, con el objetivo de estimular cambios en la conducta.

Palabras clave: Ética. Bioética. Experimentación animal. Animales de laboratorio. Alternativas al uso de animales. Comités de atención animal.

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Declaram não haver conflito de interesse.

Legislation related to animal ethics

Until the 1970s, when the discussion about animal bioethics began in Brazil, research and teaching centers were essentially based on the common sense of the researcher as a guide for laboratory manipulation¹. Law 6,638/1979², the only one related to the theme at the time, gave only recommendations, without punitive character. Only in 2008, the National Congress passed Law 11,794³, which regulated the use of animals for teaching and research.

Following this law, there were several changes, such as the creation of the Conselho Nacional de Controle de Experimentação Animal – National Council for Control of Animal Experimentation (Concea) and the obligation for institutions that use animals for research to install Comissão de Ética no Uso de Animais – Ceua (Animal Ethics Commissions), enrolled it in the Registry of the Institutions for the Cadastro das Instituições de Uso Científico de Animais – Scientific Use of Animals (Ciuca). In addition, among other measures, penalties were imposed in case of non-compliance with the law^{1,3}.

Despite the efforts of many entities to make existing legislation better known, there are still several difficulties in putting this into practice. The problem begins at undergraduate courses because, despite handling animals in classes and research, most students are unaware of Law 11,794/2008³. Thus, this article aims to demonstrate the importance of knowledge of this standard for undergraduate health. To this end, issues fundamental to their understanding and the role of advisors, teachers, and students in the proposed activities will be discussed.

Law 11,794/2008: main requirements

As mentioned, Law 11,794/2008³ (known as the “Arouca Law” in reference to its rapporteur, Sérgio Arouca) established various rules and guidelines for activities involving animal experimentation. The main deliberations are summarized in the following section.

Concea attributions

One of the main consequences of Law 11,794/2008³ was the creation of Concea^{1,3}. With activities covering the entire national territory, the council is made up of 28 counselors, representatives of ministries, the scientific community and legally established animal protection societies^{1,4,5}. The

ministries with representation in the entity are Science, Technology, Innovations and Communications; Education; Environment; Cheers; and Agriculture, Livestock and Supply. Organizations with counselors include the Conselho Nacional de Desenvolvimento Científico e Tecnológico – National Council for Scientific and Technological Development (CNPq), the Conselho de Reitores das Universidades do Brasil – Council of Rectors of the Universities of Brazil (CRUB), the Academia Brasileira de Ciências – Brazilian Academy of Sciences (ABC), the Sociedade Brasileira para o Progresso da Ciência – Brazilian Society for the Progress of Science (SBPC), the Federação de Sociedades de Biologia Experimental – Federation of Experimental Biology Societies (Fesbe), the Sociedade Brasileira de Ciência em Animais de Laboratório – Brazilian Society of Laboratory Animal Science (Sbcal/Cobea) and the Federação Brasileira da Indústria Farmacêutica – Brazilian Federation of Pharmaceutical Industry (Febrafarma)⁴.

The Concea has quarterly meetings in which its members deliberate on different issues related to the Arouca Law³ and analyze alleged administrative violations of individuals and legal entities, classifying cases of transgression as mild, serious or very serious. The counselors also prepare texts for public consultations published in the Federal Official Journal. Prior to the officialization of the rules, researchers, teachers, and the general society have the right to comment on the council’s website⁶. These, in turn, are published as “Technical Guidelines” and “Normative Resolutions” for those who work with animals. The texts are objective and practical to facilitate the understanding and the accomplishment of the activities^{1,4}.

Function of the Ceua

The Ceua must be established in institutions before the beginning of research, or teaching activities, with animals, through registration in the Ciuca, which is now required by Decree 6.899/2009⁷. Ethics committees should be composed of biologists, doctors –veterinarians, teachers and researchers in the area and a representative of animal protection societies. Among others, the Ceua must, *within the scope of its attributions, enforce the provisions of this law [11,794/2008] and other standards applicable to the use of animals for teaching and research, especially in the Concea resolutions*⁸.

Therefore, these commissions are responsible for approving or rejecting projects and teaching activities using animals and ensuring compliance with the provisions of the Arouca Law³, conducting surveys and

inspections. At universities, the Ceua reports to the rectory or board of directors, who, in turn, report to the Conceia. That is, there is a hierarchy to be followed and each organ responds to which it is subordinated. Thus, it is verified the importance of ethics committees so that research and practical classes comply with what is established by the Conceia and normative resolutions. It is a legal obligation to report to Ceua all teaching and research activities that use animals, and require its permission to perform them^{1,4}.

Penalties

In addition to carefully regulating the use of animals in the laboratory and teaching activities, Law 11,794/2008³ differs from the background by establishing punishments for those who violate it^{1,2}. Thus, many students' lack of knowledge of the legislation is not only a shortcoming concerning bioethics but can also lead to consequences if they and the institution even involuntarily disregard the current rule⁹⁻¹². Articles 17, 18 and 19 of chapter IV of the law bring some of the punishments:

Article 17. The institutions that perform activities regulated by this Law are subject, in case of violation of its provisions and its regulation, to administrative penalties of:

I - admonition;

II - fine of R \$ 5,000.00 (five thousand reais) to R \$ 20,000.00 (twenty thousand reais);

III - temporary interdiction;

IV - suspension of financing from official sources of credit and scientific promotion;

V - definitive interdiction.

(...)

Art. 18. Any person who improperly carries out activities governed by this Law or participates in procedures not authorized by Conceia shall be liable to the following administrative penalties:

I - admonition;

II - fine of R \$ 1,000.00 (one thousand reais) to R \$ 5,000.00 (five thousand reais);

III - temporary suspension;

IV - definitive prohibition for the exercise of the activity regulated in this Law.

Art. 19. The penalties provided for in arts. 17 and 18 of this Law shall be applied according to the gravity of the infringement, the damages arising therefrom, the aggravating or attenuating circumstances and the antecedent of the infringer³.

That is, the violation of the law can lead to a financial punishment for both the student and his advisor, and the institution, as well as prohibit the conduct of animal research. The penalties clearly reflect the responsibility of the researcher, which reinforces the importance of knowing the Arouca Law in depth.

Student participation in teaching and research

Animals can be used in two ways in the undergraduate context: in practical classes or research activities. Each of these modalities has peculiarities regarding student participation, as described below.

Practical classes and excuse of conscience

Like in research, practical class activities that use animals must be approved by the Ceua and meet the criteria of relevance, common sense, and need established by the Conceia⁴. These activities should be motivated to facilitate students' understanding through observation, in real-time, of certain biological mechanisms. However, many young university students have recently been reluctant to collaborate with this practice^{12,13}, as there are alternative resources to avoid using animals, such as filming (one-time use of the animal) and practices as effective as the traditional ones¹⁴. Also, the dissemination of themes related to ethics and animal welfare has influenced this decision of the students.

The criteria the Ceua uses for approving teaching activities are based on the principle of 3Rs (reduction, refinement, and replacement)^{15,16}. Thus, from both a legal and ethical perspective, any project involving the use of animals for teaching and research should propose alternative methods, where applicable¹. Following this principle, in response to the movement of students and bodies linked to research and education, a note was published in the Diretriz Brasileira para o Cuidado e a Utilização de Animais para Fins Científicos e Didáticos – Brazilian Directive for the Care and Use of Animals for Scientific and Didactic Purposes (DBCA), in which it is assumed that teachers are supposed to provide alternatives for students who choose not to participate in activities involving the use of animals¹⁷.

The Conceia also published, in 2016, a note on student participation in these activities, establishing the “excuse of conscience”:

5.1.1. Institutions that produce, maintain or use animals for teaching or scientific research throughout the National Territory should develop mechanisms that enable the governing body of the Institution or its representative to ensure compliance with the legislation and this Guideline. These mechanisms should include:

(...) Make alternative learning assessment methodologies available to students who, for lack of conscience, do not participate in teaching activities involving the use of animals¹⁸.

The note published by Conceia reflects the agency’s move to encourage alternative teaching methods. In addition to the positioning of the entity, the attitude reflects the demands of present-day society, such as the claim by students of the right not to participate in activities that use animals unnecessarily.

Activities in research and scientific initiation

Unlike practical classes, undergraduate research activities are not compulsory – the student who pursues these activities does so spontaneously. Therefore, being the elective scientific initiation, it is expected that those who choose to develop projects involving animals do their work properly, knowing – or being proactive to learn – the ethical and legal requirements of this type of research.

Thus, undergraduate students can implement standardization in animal bioethics in the environment in which they operate. However, these rules must reach the student: the interest in animal manipulation does not necessarily make the undergraduate student clear about the laws involved in the activity. Therefore, the guidance of the responsible teacher and the guidelines of the educational institution are important in this process. It is up to the advisor to know the law to instruct the student before the beginning of the activities, and the institution to supervise if the teachers effectively know and comply with the legislation and good practices with animals, ensuring that the information reaches the students.

Everyday practice: the effectiveness of the Law 11,794/2008

In everyday practice, one of the most significant impacts of Law 11,794/2008³ was the change in

the mentality of researchers in academia. Common sense is no longer the only guide to animal welfare, being replaced by rules and legal provisions^{3,4}. Still, it is necessary to improve the law and establish new discussions, addressing other aspects and refining pedagogical apparatus to better disseminate it. Years after the implementation of the standard, there is still a significant portion of researchers with difficulties to accept it¹⁹⁻²¹. The justifications refer to bureaucratic obstacles (sometimes linked to the institutions and research groups themselves) and to the complexity of adapting the research lines, hypotheses, and scientific aspirations to the current norm¹.

Students, in turn, should be the focus of these measures. As mentioned, in most institutions, especially universities, they are responsible for manipulating animals in research. It is up to the Ceua, the Conceia and the educational and research institutions themselves to ensure that information regarding Law 11,794/2008³ reaches these students^{1,3}. For although there are ways to spread the law, such as institutional e-books and official Ceua pages, there are marked gaps in students’ knowledge of animal bioethics¹.

Thus, concrete assessments and research on students’ knowledge are needed to establish mechanisms that solve the problem. It is necessary to assign responsibilities concerning the teaching of Law 11,794 / 2008³ and other topics of bioethics. Both advisors and students should be proactive in seeking to know the ethical implications of animal experimentation.

Educational and research institutions, which can provide adequate training for students and teachers, should also be held accountable. Unfortunately, the Arouca Law³ is not entirely clear as to who is responsible for teaching these topics, which is why the three parties involved (students, advisors, and institutions) occasionally fail to spread this knowledge. By broadly approaching this situation, it will be possible to use various methods to reach undergraduates. In this process, both existing and new forms of dissemination should be encouraged.

Undergraduate students rarely have any previous direct and scientific contact with animals, which makes them especially unprepared for bioethics issues. Certainly, it is necessary to start at some point, because invariably those who work ethically and professionally with animals will have moments of theoretical enlightenment and practical training. This period requires caution and responsibility (both from the student and the counselor) and should be treated with due care and caution by the academic community.

It is necessary to collect data that demonstrate how many students lack knowledge in animal bioethics and who they are, seeking the reasons why this information does not reach them. These and many other questions await clarification and, if answered, will be the first step to effectively implement the resolutions of Law 11,794/2008³, improving the quality of research and teaching practices. This will allow Brazil to reach the level of countries that truly value animal bioethics and the scientific approach based on uniform and reliable data¹.

To achieve this goal, it is necessary to foster ethical discussions and reflection on the 3R principle, seeking to apply it to the reality of research with experimental animals (for example, by minimizing animal suffering while fulfilling the research objective). These debates, studies, and practices will enable students to develop their learning about the process of producing and building science.

Animal bioethics based research, besides being more qualified, reflects the researcher's respect for the beings used in research. In this sense, it is worth mentioning Sánchez González, professor at the Universidad Complutense de Madrid: *although we do not know that rights have animals to be respected by man, what does not admit doubts is the fact that man, being a man, has the obligation to respect animals*²². Therefore, the scientist who values animal welfare demonstrates his care in developing hypotheses, methods, and faithfulness of results.

Law 11,794/2008: practical measure to the undergraduate context

Different ways of stimulating knowledge – and hence establishing better research and teaching practices – can be put in place to inform and sensitize undergraduate students involved in projects that use animals. For those seeking scientific initiation, for example, a short course could be given before the beginning of the project. The training would not only address the theoretical bases of Law 11,794/2008 but would prepare students for practical situations, teaching behaviors to check the welfare of animals and conditions of the place where they stay (temperature, lighting, hygiene, food etc.).

The very dissemination of the law through the Internet, with e-books, posts on the institution's websites and social networks, as well as specific events and moments of discussion, is an effective way to promote animal bioethics. Also, the knowledge of counselors and students must be

assessed. Finally, lectures on subjects with a high frequency of animal experimentation students can help to spread the principles of bioethics, or even offer elective discipline on the subject.

All these measures are part of the animal care movement, starting from universities to reach society in general, encouraging the adoption of laws that reflect bioethical values and principles of respect for beings used in research. Finally, we reiterate that the search for knowledge depends on both the advisor and the students, who must be willing to seek information to improve themselves.

Final considerations

Law 11,794/2008³ was an indisputable advance in Brazilian bioethics. All the organs, groups, commissions and entities that support it (Concea, Ceua, Animal Protection Society, SBPC, SbcAl, among others) are indispensable players for a change in mindset towards animal welfare. In addition to the action of these entities, it is necessary to provide for penalties to violators, whether in the form of warnings, fines or definitive prohibitions.

The penalties guarantee the effectiveness of the Arouca Law³, establishing a degree of seriousness never conferred to the care of laboratory animals nationwide. But beyond the penalties, it is necessary to encourage the production of educational material and the holding of events that spread the knowledge of the law. Although they already exist, these strategies can be intensified and become more frequent.

It is concluded that, despite all advances and mechanisms of awareness about animal bioethics, legal determinations still have low reach among university students⁹⁻¹², including those dealing with animals. Consequently, students involved in this type of research must have a better knowledge of the Law 11,794/2008, its requirements, recommendations, and penalties.

Law 11,794/2008³ will only become fully effective when all those handling animals in their investigations – researchers, laboratory technicians, vivarium technicians, and especially students – are aware of their obligations and how to perform their work properly. For this, it is essential to conduct research and evaluate the level of awareness of these groups. Only in this way will it be possible to accurately devise methods to instruct and inform them to ensure animal welfare. This will be another step towards consolidating Brazilian animal bioethics.

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Participation of the authors

Nicole Dittrich participated in the project design, literature review and in writing the article. Gabriel Natan Pires served as co-advisor and collaborated in writing and proofreading. Monica Levy Andersen contributed to the project design, guidance and consultancy on bioethics, and article review. Sergio Tufik acted in project design and supervision.


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