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Focus

Application in French law of the new European regulations on the protection of animals used for scientific purposes: What progress has been achieved for animals? What constraints does this impose on research?

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Following European Directive 2010/63/EU, the French implementing legislation on the protection of animals used for scientific purposes was published in February 2013. These new regulations impose a number of limitations and constraints on scientific research and make the issue of animal suffering a primary concern.

Introduction

After two years of deliberation and collaboration between government authorities (the French Ministries of Agriculture and Research), professionals and animal welfare associations, the implementation of Directive 2010/63/EU (Directive, 2010) on the protection of animals used for scientific purposes was confirmed on 7 February 2013 with the publication of French texts in the Official Journal of the French Republic. This legislation takes the form of:

- a decree (Decree, 2013) on the protection of animals used for scientific purposes that *"establishes the conditions relating to the species concerned, the origin of animals, housing and care conditions, as well as the experimental procedures that must be complied with by user, breeder and supplier establishments if they are to be authorised to perform experimental procedures on animals or to raise or supply animals for this purpose. It lays down the conditions for accreditation and control of breeder, supplier and user establishments for animals used or intended to be used for scientific purposes.";*
- five inter-ministerial orders (Order, 2013a; Order, 2013b; Order, 2013c; Order, 2013d; Order, 2013e).

Since animal welfare is a value of the Union upheld by Article 13 of the Treaty on the Functioning of the European Union, the new French regulations resulting from European Directive 2010/63/EU are based on the rule of the three Rs (Russell and Burch, 1959): "Replacement" of animals whenever possible, "Reduction" in their numbers in the procedures performed and "Refinement", i.e., limiting the harm caused to animals. These new regulations are resolutely focused on animal welfare and introduce significant changes in the use of animals for experimental purposes.

The provisions of the new French regulations apply when animals are used or intended to be used in experimental procedures, or when they are bred so that their organs or tissues may be used for scientific purposes. They concern vertebrate animals, and for the first time, larval forms able to feed themselves, foetal forms of mammals as from the final third of their normal development, and cephalopods.

On a practical level, a number of measures are to be introduced within user establishments (formerly known as animal experimentation establishments), as well as in supplier and breeder establishments, another new feature of these regulations.

Responsibilities and animal welfare

The provisions of this new regulatory framework include (1) the appointment of an animal welfare manager and (2) the setting up of a body responsible for animal welfare within each user, supplier and breeder establishment. Many tasks are delegated to these new functions. The manager is in charge of monitoring animal welfare in the establishment, supervising and following up authorised projects and monitoring the competence of staff designing or conducting experimental procedures, applying these procedures to animals, providing care for animals and killing them. The new body is responsible, among other things, for:

- advising staff on issues relating to animal welfare, care and housing,
- advising staff, in particular staff designing experimental procedures, on the implementation of the 3Rs,
- informing staff of technical and scientific developments relating to the application of this rule.

This body must also monitor the progress and results of projects using animals conducted within the establishment, and provide advice on animal rehoming programmes (that is the possibility that private individuals adopt animals (for domestic species) or the possibility to place animals in appropriate structures (for livestock and wildlife), when their health allows it at the end of the study. Although both functions are important and make a major contribution to animal welfare, the fact remains that this entails a considerable amount of work, which can be difficult to deal with in the current economic and budgetary climate in institutions - especially those in the public sector - required to use animals for experimental purposes.

Staff competence

Another important point concerns the competence of staff working in animal experimentation that results from their initial training, participation in a specialised animal experiment training programme (carried out no later than the year after they start work) and continuing education. The latter involves a minimum of three days of training every six years. Although at first sight this does not seem very much, this new provision is an important step that will enable all staff (not only scientists, but also technicians and animal attendants) to maintain their knowledge and keep abreast of new technologies and advances in the fields that concern them. All staff skills and training will be recorded in a skills booklet specific to each person, proving that their competence effectively matches their functions.

Authorisation of projects

One of the major changes to the previous system is the requirement to obtain authorisation prior to carrying out any project involving the implementation of one or more experimental

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procedures using animals. The project authorisation file includes a non-technical summary providing information on the project's objectives and the number and type of animals used. As this summary is intended to be published on the Ministry of Research's website and will therefore be accessible to the general public, scientists need to be vigilant to avoid disclosing confidential information.
Projects are authorised by the Ministry of Research for a maximum of five years. In another new development, when issuing authorisations this Ministry now relies on an ethics evaluation carried out by the ethics committee for animal experimentation affiliated to the establishment where the project will take place. In practical terms, all establishments conducting projects involving the use of animals for experimental purposes should therefore appoint an ethics committee, which must of course be operational and registered with the Ministry of Research. Most public and private French research organisations already have ethics committees, which play a vital role in ensuring that projects are undertaken while respecting ethics and animal welfare. The new regulation therefore formalises the work of these bodies that were already operating in compliance with the National Charter on the ethics of animal experimentation, whose philosophy is very close to the European (Directive, 2010) and French regulations (Decree, 2013). Currently, projects are submitted to the Ministry of Research by post, whereas online completion of applications and direct electronic submission are expected to be set up in the future, which should facilitate the process.

Care and housing

With regard to animal care and housing conditions, the new regulations entail a review of the requirements with the aim of improving the welfare of animals both in experiments and in breeding (Order, 2013a, Annex II). Establishments have until 1 January 2017 to acquire housing materials that meet the required standards. In addition, establishments are now required to implement appropriate enrichment techniques allowing the animals to express a wide range of normal behaviour. The establishment's *enrichment programme* should be regularly reviewed and updated. Individual housing may be allowed in accordance with the authorised project but should be limited as much as possible, and visual, auditory, olfactory and/or tactile contact should be maintained with other animals. Last but not least, the animals must be *checked daily* by a competent person. In fact, daily checks are already in place in organisations experimenting on dogs, cats, ruminants and non-human primates, and during projects potentially causing suffering in test animals (projects classified as 'severe'). However, these checks were not previously performed in most animal facilities housing rodents, species that are untroubled by the automatic distribution of food and can do very well without the presence of humans. This new requirement may cause problems in the organisation of work, particularly in smaller establishments, while the benefits are questionable for rodents, which are known to prefer being left alone to excessive handling and inspections.

Non-human primates (NHPs)

Finally, Non-human primates (NHPs) have a *special status* and are subject to specific measures. After much debate and as requested in the report on Directive 86/609/EEC (Evans, 2002; Directive, 1986), Europe, and by extension France, decided to consider NHPs as a special group of species governed by specific provisions. The first measure concerns the purpose of procedures involving NHPs that concern the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening human diseases. The second measure is the requirement for a scientific demonstration explaining that the purpose of the experimental procedure cannot be achieved by the use of species other than those belonging to the order of primates. Furthermore, the use of great apes (gorillas, chimpanzees and orang-utans) is prohibited except in the event of a specific waiver subject to approval from the European Commission. While the special protection of NHPs is a good thing because of their phylogenetic similarity to humans, it should however be considered that NHPs are not the only animals capable of experiencing stress, pain and suffering, and of emotions more generally. Does the special protection afforded to NHPs result in less protection for other animal species? Although this was not the intention of Directive 2010/63/EU and the ensuing French regulations, it appears that this is an indirect consequence.

Conclusion

In recognising animal suffering, these new regulations appear to be a step forward for the protection of animals used for scientific purposes, in terms of both improved standards of care and housing and the mandatory ethics evaluation for projects carried out by French scientists. It is worth noting, however, that when faced with increased costs and administrative burdens, questions should be asked about the future position of Europe and France in a context of increasing globalisation of research. Indeed, some countries are positioning themselves as possible alternatives to carrying out research projects in Europe, in particular research projects involving NHPs, which could not only lead to the "offshoring" of research, but also to less protection for animals in countries where the regulations in this area are not as advanced as in Europe. In addition, while animals continue to be essential models for fundamental and applied research, the fact remains that in recent years there has been great progress in the development of alternative methods to animal testing. One example of this is the establishment in 2007 of the national platform for the development of alternatives to animal testing (FRANCOPA, http://www.francopa.fr/web/francopa?page=home&out=txt&languageIhm=fre), which itself is a member of the European Platform, ECOPA (http://www.ecopa.eu/).

Bibliography

Arrêté, 2013a. Arrêté du 1er février 2013 fixant les conditions d'agrément, d'aménagement et de fonctionnement des établissements utilisateurs, éleveurs ou fournisseurs d'animaux utilisés à des fins scientifiques et leurs contrôles. NOR: *AGRG1238753A*

Arrêté, 2013b. Arrêté du 1er février 2013 fixant les conditions de fourniture de certaines espèces animales utilisées à des fins scientifiques aux établissements utilisateurs agréés. NOR: *AGRG1238724A*

Arrêté, 2013c. Arrêté du 1er février 2013 relatif à l'acquisition et à la validation des compétences des personnels des établissements utilisateurs, éleveurs et fournisseurs d'animaux utilisés à des fins scientifiques. NOR: *AGRG1238729A*

Arrêté, 2013d. Arrêté du 1er février 2013 relatif à la délivrance et à l'utilisation de médicaments employés par les établissements agréés en tant qu'utilisateurs d'animaux à des fins scientifiques. NOR: *AGRG1240332A*

Arrêté, 2013e. Arrêté du 1er février 2013 relatif à l'évaluation éthique et à l'autorisation des projets impliquant l'utilisation d'animaux dans des procédures expérimentales. NOR: *AGRG1238767A*

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Décret, 2013. Décret n°2013-118 du 1er février 2013 relatif à la protection des animaux utilisés à des fins scientifiques. NOR: AGRG1231951D

Directive, 2010. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

Directive, 1986. Council directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.

Evans J. 2002. Report on Directive 86/609 on the protection of animals used for experimental and other scientific purposes (2001/2259(INI)). 13 pages.

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/evans_report.pdf

Russell WMS, Burch RL. 1959. The principles of humane experimental technique. Johns Hopkins University, United States. See online edition:

http://altweb.jhsph.edu/pubs/books/humane_exp/het-toc