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Legislation of animal use - Developments in Europe

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Abstract

Before 1986 legislation on the protection of animals used in research and testing existed in only a limited number of European countries. In 1986 the European Parliament adopted the *Council Directive 86/609 on the protection of animals used for experimental and other scientific purposes* (Directive 86/609). As a consequence all EU Member States were obliged to implement legislation as to protect laboratory animals or to adapt the existing legislation so that the requirements as laid down in Directive 86/609 were met. Developments in the field of biomedical sciences and advancing knowledge on the physical, behavioural and psychological needs of animals require a revision of Directive 86/609. Also animal rights groups, acting as advocates for animals, are demanding revision of the Directive. The process of this revision already started in 2002 and is now in its final stage. Part of the preparative work consisted of a consultation of experts and citizens through the internet. The contours of the revised Directive are becoming clear but the final decisions for implementing the new provisions must still be taken. In this paper some major issues of the current Directive 86/609 and the options for revision, as these have been put forward for consultation by the European Commission, are presented.

Keywords: legislation animal experiments, revision Directive 86/609, Europe

Introduction

The use of animals for research and testing is a controversial issue in society. In a democracy, legislation, based on an open debate by representatives of the citizens, is a major instrument in balancing potential conflicts of interest. When preparing legislation as to regulate the use of animals in research and testing it is essential that the voices of those whose priority is the health and welfare of humans and the voices of those who are defending the rights of animals are taken into account. In 1986 the European Parliament adopted, for the first time, legislation aiming at the protection of animals used for experimental and other scientific purposes (Directive 86/609) (1). This Directive contains provisions on the care and accommodation of laboratory animals, the competence of persons involved in the care and use of animals, the use of alternative methods, including those that can prevent animals from suffering pain and distress and many others. The provisions of the Directive must be implemented in national legislation by all 27 European Union (EU) Member States.

Also the Council of Europe approved regulations on the protection of vertebrate animals used for experimental and other scientific purposes (Convention ETS 123) in 1986 (2). The Council of Europe consists of 47 Member States. In contrast to Directive 86/609, the provisions of the Convention do not need to be implemented, unless a Member State has ratified the Convention.

In this paper the focus is on Directive 86/609 .

Revision of Directive 86/609

In 2002 the European Commission was called by the European Parliament to prepare a proposal for a revision of Directive 86/609. Several reasons were mentioned, among these that different Member States apply different standards to authorize, monitor and review animal-based projects and that a formal system for a critical review of such projects is often lacking. Also the effectiveness of controls was reported to differ between Member States as well as the application of the three Rs (replacement; reduction; refinement). New knowledge on the physical, behavioural and psychological needs of animals also required an update of Directive 86/609.

In 2003 the Commission started to collect background information for the revision. Experts from Member States were invited to cooperate with the Commission as to provide input for the various aspects. These experts are specialists working in the field of laboratory animal science, research, industry and/or animal welfare. Four sub-groups of experts have prepared a report on the following sub-areas:

Scope of the Directive; Authorization of institutes, projects and personnel; Ethical review of projects; and Cost-benefit analysis/severity of procedures (3).

As part of the preparatory work for the revision, the Commission also requested the Scientific Committee on Animal Health and Animal Welfare (SCAHAW) to give an opinion on the welfare of non-human primates used in experiments (4), whereas the Animal Health and Animal Welfare Panel (AHAW) of European Food Safety Authority was mandated to give a scientific opinion on some specific questions, like whether the scope should also include invertebrate species and foetal/embryonic forms, which animals should be purpose bred and which procedures can be identified as humane methods of euthanasia (5).

In 2006 an independent consultancy organization (PROGNOS) was commissioned with the task to perform an impact assessment. The objective of this impact assessment was to critically review the options for revision of the Directive and to provide indications as to the related benefits and costs of the various options for stakeholders and animals.

As part of the impact assessment the Commission, in collaboration with PROGNOS, organised an internet consultation. The consultation consisted of two separate questionnaires, one for all interested citizens of the EU and one for experts in the area of animal testing and animal welfare. The citizens' questionnaire consisted of questions asking the views of the respondents on different aspects of animal experimentation and the perception of the level of animal welfare both at national as well as EU level. The expert consultation consisted of more specific questions. These questions were mainly based on the reports prepared by the above mentioned four sub-groups, the opinions of SCAHAW and the AHAW Panel and preliminary information collected by PROGNOS. The internet consultation was meant to obtain additional input on the possible impact of different policy options for the revision. The results of the internet consultation can be found on the internet (6,7).

All the information is now being reviewed by the Commission and used to draw the final proposal for the revision of the Directive. Below an overview of some major options for the revision are summarised. At this stage it has not been decided yet, which of the options will be implemented in the new Directive. A proposal for the revision must first pass the internal Commission Consultation and also needs the approval of the EU Parliament.

It should be noted that EU Member States all have their own national legislation. The national law must, at least, meet the requirements laid down in the Directive, but provisions at the national level may go beyond those of the Directive, a situation that is presently already the case in several countries.

1. Scope of the Directive

In the current Directive an 'animal experiment' is considered to be an experiment with a living non-human vertebrate (including free-living larval and/or reproducing larval forms) which may cause pain, suffering, distress or lasting harm to the animal and which is aiming at the development, manufacture, and safety testing of drugs, foodstuffs and other substances; or at the avoidance, prevention, diagnosis or treatment of diseases in man, animals or plants; or at the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or at the protection of the natural environment in the interests of the health or welfare of man or animal.

Animals used in basic research are not protected by the current Directive. Neither are animals used in education and training. Also invertebrates are not covered by the Directive.

In the EU yearly between 11 and 12 million vertebrate animals are used for experimental purposes. About 35% of these animals are used in basic research or for education/training programmes. Options proposed for the revised Directive are to also include animals used in basic research (including animals used in procedures that result in the production of a new genetically modified line) and animals used for education and training. Most Member States (80%) have already included the animals used for these purposes into their national legislation.

The number of invertebrate animals used in EU Member States is not known.

EFSA has recommended an extension of the scope so that selected invertebrates species (*Cyclostomes, Cephalopods and Decapod crustaceans)* would also be protected by the Directive (5).

2. Authorisation

The current Directive does not require compulsory authorisation of projects. Only in case an experiment may cause prolonged and severe pain, it has to be declared and justified to, or specifically authorised by, the authority. Yet, some form of authorisation is currently required by law in 21 Member States, but the procedures for authorisation are quite different. In some countries projects are authorised at a national level, whereas in other countries authorisation is granted to institutes or persons with a licence for performing animal experiments. Most Member States have an authorisation systems for projects in combination with a procedure for the authorisation of establishments and personnel.

The options proposed for the revised Directive include mandatory authorisation of individual projects with compliance check and authorisation of groups of projects in case projects are executed for regulatory

testing as requested by (EU) legislation.

In order to harmonise the situation on authorisation of projects, the compliance check should then, as a minimum, include assessment of elements such as whether the authorisation of the establishment and of the personnel is valid (the provisions for authorisation of establishments and personnel are also subject of revision), whether the housing and care standards are adequate, an animal welfare officer is working in the establishment, a veterinarian is named and available on request and if a scheme for local ethical review process throughout the project lifetime is in place. Also, a positive opinion based on a detailed evaluation by an ethics committee should be part of the authorisation procedure (see below).

At which level (national/ regional or decentralised) authorisation is executed may then be determined by the individual Member States.

3. Ethical review

There are no provisions in the current Directive for the ethical evaluation of projects.

Yet, in 13 Member States an ethical evaluation prior to the start of a project is required through national legislation and there are another eight Member States where some form of ethical evaluation of projects takes place without the force of legislation. The system, however, differs greatly between countries. Differences exist in the organisation level (local; regional; national) or the research level (procedure; project; programme) at which ethical evaluation is implemented. For example in the Netherlands there are about 30 local animal ethics committees, each consisting of at least seven members, which have the task to evaluate the ethical acceptability of proposed animal experiments. In Denmark this task is commissioned to one national committee with 11 members. Also, elements that are integrated in the evaluation process may differ between countries or even within countries between different committees. As a consequence the opportunities for the implementation of the three Rs are not always fully exploited.

Most of the stakeholders who have responded to the expert questionnaire of the internet consultation agree that the existence of an effective ethical review process should be mandatory in every European country. The first step of such a process is the ethical evaluation of animal use, prior to the start of a project. An important option for the revision of the Directive is to make the ethical evaluation of projects mandatory. Ethical evaluation of projects is seen as a key instrument to improve both the quality of experiments and the welfare of laboratory animals. Its primary goal is to ensure that the use of animals is justified, weighing the scientific or social values of the experiment against the potential negative effects on the welfare of animals involved. The proposal for the revised Directive includes provisions to ensure that the project is justified and carried out in the most humane manner, thus fully incorporating all opportunities of reduction, replacement and refinement. A harm/benefit analysis is proposed to be part of the ethical evaluation of projects. The ethical evaluation needs input from experts in various areas (e.g. scientific field for which the animals will be used; experimental design/statistics; veterinary practice; animal ethics; alternatives).

Besides a proposal for establishing a system aiming at the ethical evaluation prior to the start of the project it is also proposed that establishments must set up their own permanent ethical review system, conducted by a team consisting of the designated veterinarian, the person(s) responsible for the welfare and care of the animals and a scientific member of the establishment. The task should be to provide in-house advice on the humane use of animals and to keep the establishment keen on options of implementing new developments in the field of replacement, reduction and refinement.

In addition to the provisions for the initial ethical evaluation of projects and the permanent ethical review system, there is also an option foreseen for a retrospective ethical evaluation of specific projects. Projects using non-human primates or projects that involve severe suffering might be considered for a mandatory retrospective ethical evaluation.

4. Transparency

With regard to transparency, the current Directive only requires that a statistical report is made publicly available. Basic statistical information on number of animals per species and purposes for which these animals are used are made available, mostly through yearly reports published by the national government.

In order to meet the increasing demand for more openness in the field of animal experimentation it is proposed that the revised Directive, in addition to more detailed annual statistical data, requires the publication of the local guidelines for ethical review and other procedures that are established to promote the humane use of animals. And also that persons conducting projects involving the use of animals are required to provide anonymous non-technical summaries of these projects. These summaries must include information on the number and type of animals to be used, the predicted benefits and the potential harm and how the requirement on replacement, reduction and refinement is taken into account.

As a consequence, it is foreseen that the public will get access to more detailed information on the use of animals in research and testing.

5. Housing and care

Annex II to the current Directive contains non-binding guidelines for the housing and care of laboratory animals. These guidelines are identical to those of Appendix A to the 1986 *Convention for the protection of vertebrate animals used for experimental and other scientific purposes* (ETS 123) of the Council of Europe. Sixteen out of the 27 EU Member States have ratified Convention ETS123. For these countries, the provisions as laid down in Appendix A are considered as minimum compulsory. In others these still have the status of non-binding guidelines. The Council of Europe has recently revised Appendix A (8). In the revised guidelines cage sizes have significantly increased and there is more emphasis on group housing and enrichment. The EU has ratified the Council of Europe Convention ETS123 and adopted in June 2007 these guidelines as Recommendations. It is proposed that these Recommendations, like Annex II of the current Directive, will become part of the revised Directive.

6. Education and training

The current Directive states that 'persons who carry out experiments or take part in them and persons who take care of animals used for experiments, including duties of a supervisory nature, shall have appropriate education and training. In particular, persons carrying out or supervising the conduct of experiments shall have received instruction in a scientific discipline relevant to the experimental work being undertaken and be capable of handling and taking care of laboratory animals; they shall also have satisfied the authority that they have attained a level of training sufficient for carrying out their tasks'. The Federation of European Laboratory Animal Science Associations (FELASA) and the Council of Europe, recognising that qualified and well-trained personnel is an essential prerequisite for animal welfare and the quality of science, have formulated minimum requirements on education and training for different categories of personnel (9,10). As an example, for the investigator who is responsible for the design and performance of animal experiments, the minimum standard on competence should be based on a graduate study at the level of MSc in one of the biomedical disciplines and a course on laboratory animal science of at least 80 hr. The contents of the course should include topics like biology and husbandry of laboratory animals, gnotobiology and diseases, design of animal experiments, experimental techniques, anaesthetics and analgesia, alternatives, ethical aspects and legislation. All Member States have set (minimum) legal requirements for the competence of personnel responsible for the design and performance of experiments. In some Member States the system is in accordance with the FELASA guidelines. The current Directive, however, does not define competence and does not give specific requirements for education and training. Consequently, the level of education and training differs significantly between Member States. In the UK, Portugal, Ireland, and Denmark the academic degree is not specified. Also, the recommended basic course in laboratory animal science of 80 hr has not been made mandatory in Germany, Spain Italy or Portugal. In other countries such as Sweden, Denmark, Finland, France, The Netherlands, Belgium, and the UK, a course has been made mandatory by law, but the length of the course varies (40-120 hr). Harmonisation, based on a standardized set of (minimum) requirements, seems important, not only because the diversity that presently exists hampers the free exchange of scientists between Member States, but also because such harmonisation will have a positive effect on the welfare of animals, especially in those countries where formal requirements have not yet been clearly formulated or implemented. This not only counts for scientists, but also for other personnel involved in the use and care of laboratory animals. It is proposed that the revised Directive provides guidance with regard to minimum requirements on contents (mentioning the areas of expertise) and length of training that is required for obtaining initial competence for the various categories of personnel and also with regard to the period of time the authorisation is valid.

7. Use of non-human primates

According to Art. 7.3 of the current Directive experiments on animals taken from the wild may not been carried out (unless experiments on other animals would not suffice for the aims of the experiment). This also counts for non-human primates. The majority of non-human primates used in research and testing are F1 macaques (F1 is the progeny of a mating between two wild-caught animals). These animals are imported from countries outside the EU. In order to discourage use of wild-caught macaques for breeding, the EU is considering a ban on F1 macaques. For the revision of the Directive a gradual switch to only allowing the use of F2 (second generation) or F2+ (following generations) is proposed. Also some form of certification of breeding establishments that are allowed to export animals to EU countries is being considered.

The use of Great Apes is presently forbidden in some EU Member States. For the revised Directive a provision is proposed as to prohibit the use of Great Apes in each of the 27 EU Member States, with the exception of the use for procedures aiming at the preservation of these species. For the other non-human primates specific provisions will be included, e.g. on authorisation, retrospective ethical evaluation, and reporting.

The above overview is a selection of options that are currently being considered for implementation in the revised Directive. Other options that have been mentioned for the revision are provisions aiming at the further promotion of animal alternatives (including the requirement that each Member State must designate a reference laboratory for the validation of alternative methods to replace, reduce and refine the use of animals), the introduction of a system to estimate the severity of procedures with the requirement that procedures entailing severe pain or suffering which is likely to be prolonged are prohibited, the limitation of the re-use of animals, intensifying of inspections, and provisions to avoid unnecessary duplication of experiments. See for more detailed information on these options the results of the expert questionnaire (7).

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