



ESF-EMRC Position Paper • 3rd Edition • February 2011

Position on the Directive on the Protection of Animals used for Scientific Purposes (2010/63/EU)

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Foreword

The aim of this position paper of the European Medical Research Councils (EMRC), the Standing Committee for Medical Sciences at the European Science Foundation (ESF), is to provide continuing input into developments resulting from the new European Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (full text adopted at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:En:PDF>).

The second ESF-EMRC position paper, published in March 2009, was a key factor in raising awareness of the implications of the revised Directive amongst scientists, research funders, corporate research organisations and patient groups, and informing the process of revising the Directive.

This new paper is aimed at the same audience. It summarises the current status of the Directive and looks forward to the next crucially important stage during which the Directive will be transposed into law and then fully implemented in the Member States.

This paper builds on previous work of the ESF^{1,2,3} and draws on documents produced by ESF member organisations at the various stages of the consultation process for the revision of this Directive. The key reference document for this paper is the Directive that was formally adopted by the European Parliament on 8 September 2010.

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Cover

Sprague Dawley Variety of White Laboratory Rat
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1. ESF Science Policy Briefing (SPB) n°9 "Use of Animals in Research", September 2000 & ESF SPB n°15 "Use of Animals in Research", August 2001 (2nd Edition)
2. ESF-EMRC "Position on the Proposed Revision of the Directive on the Protection of Animals Used for Experimental and Other Scientific Purposes (86/609/EEC)", September 2008
3. ESF-EMRC "Position on the Proposal for a Directive on the Protection of Animals used for Scientific Purposes", March 2009 (2nd Edition)

List of Abbreviations

AW: Animal Welfare Body
EC: European Commission
EU: European Union
GM: Genetically Modified
NHPs: Non-Human Primates

1. Current Status of the Directive and the Resulting Legislation

The Directive has now been finalised and published in the Official Journal of the European Union, and has entered into force as EU law. Member States must now, within two years, pass (or amend existing) national legislation to make the provisions of the Directive legally binding. Subsequently, the Directive will enter into force in Member States in January 2013 and existing legislation is expected to remain in place until that time.

The Directive sets objectives and minimum common standards, which Member States must transpose into national law. It is binding as to the result to be achieved, although the annexes can be amended through comitology (this committee system is both a political and technical process which oversees the delegated acts implemented by the European Commission (EC)).

The articles of the Directive specify the legal requirements. However, the choice of form and methods to achieve those requirements are left to the national authorities. Member states are not free to apply more stringent national measures to this specific legislation, but can maintain more stringent measures that are already in place if they are for the protection of animals.

What have we learned thus far?

The published version of the Directive is of course a compromise. Nevertheless, constant and effective provision of information by the scientific community, industry, funders, medical charities and patient groups has achieved many significant improvements over the 2008 draft published by the EC. Scientific bodies are now better organised and prepared for the challenges that national implementation will bring.

The general view now seems to be that the new Directive will continue to allow responsible research involving animals, similar to that permitted under existing legislation. Most of the controversial restrictions in the original draft Directive (November 2008) have been removed. Some examples are:

- basic research using non-human primates (NHPS) is not restricted
- re-use of animals after moderate procedures is allowed
- research involving endangered species is allowed, if the animals are bred in captivity.

Opportunities

The new Directive offers a new opportunity for harmonisation between European countries of regulatory outcomes of research involving animals. It should also make pan-EU research easier to fund, since funders will be assured of minimum welfare and ethical standards, and the authorisation of a given project will have equivalent status in different EU states. If the Directive is properly implemented, no animal research should be 'exported' from one EU state to another due to differences in the level of restrictions. However, each member state is still free to set its own regulatory processes, and it is important for the scientific community to minimise the administrative burden of these.

2. Key Elements of the New Directive

The new Directive is considerably longer and more prescriptive than the 1986 Directive. It specifies much more explicitly what is allowed and what is not. The revised Directive contains provisions on a number of key areas.

Here are some of them:

Scope: Clearly defined animals and stages covered, with special provisions in certain instances, such as endangered species, non-human primates (NHPS), dogs and cats, stray and feral, or wild-caught animals. Cephalopods are the only invertebrates included.

Purposes and procedures: Clearly defined permissible purposes, with requirements over procedures, such as the application of 3Rs (see below), selection of methods, stipulation of severity, methods of killing, limits to re-use, etc.

Establishments: Definitions of breeder, supplier and user, together with general requirements for authorisation, equipment, staffing, record-keeping, care and accommodation, authorised personnel and 'animal welfare bodies'.

Personnel: Requirements are based on education, training, supervision and competence, together with some system of national authorisation.

Projects: Research projects involving animals now require evaluation and authorisation of the proposed project – inevitably through a licensing process. Additional requirements include non-technical summaries, and in some cases retrospective assessment.

In the following sections A to D, we attempt to summarise some of the main issues which will affect the operation of the national legislation that implements the Directive.

••• **Animal Welfare and the 3Rs**

To advance humane treatment of animals used for research, William Russell and Rex Burch were the first to develop the '3Rs concept' in 1959 in their book *"Principles of Human Experimental Technique"*. 3Rs stands for the need for replacement, refinement and reduction of the use of animals in experimental work. There has been an ever increasing implementation of the 3Rs by scientists and scientific institutions. Today its widespread use by the academic community is accepted internationally as a sound basis for the humane use of animals in research. It is therefore not surprising that a number of provisions in the Directive require that the 3Rs are fully applied to further improve animal welfare and minimise animal use. Examples include the use of "alternative methods", appropriate design of experiments, choice of humane endpoints, and refinement of breeding, accommodation and care, and of methods used in procedures. In general, researchers will already be applying these principles to their experimental projects.

••• **Animal Welfare: Scientific Considerations**

Severity classification

Severity classification is set out in Annex VIII. Here the position may be difficult. Some member states may wish to push for more examples to be included, especially at the upper threshold (see below). Procedures (not projects) must be classified on a case-by-case basis, depending on the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure. Thus one view is that the application of a severity classification for a particular project is a matter of professional and scientific judgement.

• **Upper threshold restriction**

A procedure may not be performed if it involves *"severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated"*. The intention of this is to focus the minds of researchers on the amelioration of suffering, rather than create a new restriction on research. However, this clause was subject to some debate in Europe, and the current wording could leave uncertainties over some pain models that are currently undertaken routinely

for research into chronic pain states suffered by human patients such as multiple sclerosis, rheumatoid arthritis or diabetes. Restriction on these long-lasting severe pain models could have an impact on pain research. There is an exemption clause but it is questionable as to whether this should ever need to be used. We need to recognise that the creation of an additional 'super-severe' category of severity might create the tendency for authorities to move some procedures from moderate into severe.

• **Lower threshold**

The Directive has attempted to define a lower threshold of harm to animals. Therefore, the Directive does not apply to *"practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice."* However this does not constitute satisfactory guidance on non-invasive procedures, and further clarification will be necessary. It is possible that good welfare assessments of GM animals which seem phenotypically normal will mean that they fall below this threshold.

Non-human primates (NHPs)

Here the spirit of the Directive is that NHP research currently being undertaken will continue to be allowed. However, the use of NHPs in translational or applied research or toxicity testing is restricted to procedures which are *"undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings"*. The intention of this restriction was to prevent trivial research in NHPs, but it is not yet clear how this will work in practice, and there is likely to be considerable discussion and debate. The EC has offered to set up a Europe-wide working party to further clarify this issue. A debilitating clinical condition is defined as *"a reduction of a person's normal physical or psychological ability to function"*. Basic research involving NHPs, or research aimed at the preservation of the species, is not covered by this restriction.

We should avoid a list of 'acceptable' topics for applied research since scientific advances cannot necessarily be predicted. Although basic research on NHPs represents a very small number of animals, this research nevertheless provides the engine for translational advances for development in applied research.

Alternatives

Member States must ensure that, *"wherever possible, a scientifically satisfactory method or testing strategy, not*

entailing the use of live animals, shall be used instead of a procedure". The exact meaning of "a scientifically satisfactory method or testing strategy" needs to be properly determined, including practical limitations.

Re-use

This was another topic of considerable debate. The ability to re-use is to be "in accordance with veterinary advice taking into account the lifetime experience of the animal". The current view is that the final version is a good example of a 3R (reduction) because it will reduce the number of animals used.

Animal Welfare: Animal Care

Care and accommodation

The standards previously set out in ETS 123 (European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes, Council of Europe, 1986) have been made mandatory under Annex III, with variable lead-in times on cage sizes, etc. This is likely to have significant impact on costs, particularly for rodent breeding and bird housing. There are exemptions to the requirement to conform to Annex III "for scientific, animal welfare or animal health reasons". It will be for Member States to determine how such exemptions will be approved and applied. Presumably this would be part of the project evaluation by the competent authority.

Authorisation of staff

There is no mandatory authorisation of persons carrying out or supervising procedures (apparently to reduce the administrative burden and cater for different types of operations). Instead, the requirements are for the competence of staff. However, there is still a requirement for Member States to ensure, "through authorisation or by other means", that these competence requirements are fulfilled.

Training

Training of professional, responsible staff to carry out animal research remains essential. It will be in the hands of establishments. The Directive stipulates that "staff shall be adequately educated and trained before they perform any of the following functions: a. carrying out procedures on animals; b. the design of procedures and projects; c. taking care of animals; d. killing animals." Institutions may need to have their own mechanisms to monitor training and link this to competence, if they do not already.

Researchers and institutions are urged to watch this closely, since harmonisation across Europe offers the prospect of greater mobility of workers. Harmonisation opportunities already exist. For example, the Federation of European Laboratory Animal Science Associations (FELASA) promotes a Europe-wide standard for education and training. FELASA offers teaching programmes designed to enhance the competence of those working with laboratory animals (further information about the scheme at www.felasa.eu/accreditation-board). In order to contain costs and maintain the commitment of the trainees, future European training will also need to be targeted at the specific needs of individuals and their establishments.

Licensing

The arrangements for licensing of premises, projects and staff may be implemented differently in different countries. EU scientists should be watchful for national arrangements which are excessively bureaucratic or which deviate from the spirit of the Directive. Competent authorities should be encouraged to develop processing times for project evaluation and authorisation which are internationally competitive, and therefore well below the legal maximum in the Directive of 40 days.

Animal Welfare: Bureaucracy

Competent authorities and national standards

The Directive allows EU Member States to maintain provisions already in force aimed at "ensuring more extensive protection of animals... than those contained in this Directive". The intention of this is to avoid countries being forced to 'water down' their existing measures. Conversely, some countries may attempt to 'gold-plate' the Directive by bringing on more bureaucratic measures. However, additional controls are specifically excluded.

Each EU Member State must designate at least one 'competent authority' responsible for the implementation of this Directive. In each country, scientists will also have to understand who is responsible in which Ministry for this implementation.

Each Member State must have a National Committee for the protection of animals used for scientific purposes. The National Committee should "advise the competent authorities and animal welfare bodies in matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practices". It must also "exchange information on the operation of animal welfare bodies and project evaluation and share best practices within the Community".

In the context of the Directive this refers to internal bodies within establishments, and not to external animal welfare groups. The Animal Welfare Body (AWB) must include “*at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The body shall also receive input from the designated veterinarian...*”. The AWB is expected to advise staff on matters related to animal welfare, including the requirement for application of the 3Rs, and keep staff informed of relevant technical and scientific developments. It must also establish and review internal operational processes (monitoring, reporting and follow-up) and follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise on elements that contribute to the 3Rs. The word ‘ethics’ has been removed from the remit of the AWB and does not occur in relation to AWB functions; rather the emphasis is on animal welfare.

Inspections

The Directive says that Member States must carry out “*regular*” inspections of people and establishments. However, there appears to be a conflict between this requirement and the minimum requirement to carry them out on “*at least one third of users*”. In any case, the frequency of inspection must be adapted “*on the basis of a risk analysis for each establishment*”. Various factors are specified, including types and numbers of animals, types and numbers of projects, and previous compliance. Wide variation across the EU in the arrangements for inspections would be problematic.

Retrospective reviews

Retrospective reviews will be mandatory for “*all projects using non-human primates and projects containing procedures classified as severe*”. The Directive stipulates that “*retrospective assessment shall be carried out by the competent authority*”. However, for practical reasons it is desirable that much of this function be delegated to the institution’s AWB for formal reporting back to the competent authority. The AWB will be in a better position to know the current standing of any research project within an establishment.

There is considerable benefit in carrying out these reviews in terms of how each project has satisfied the 3Rs, in addition to a review of the project’s scientific quality, which is already evaluated elsewhere (e.g. by funding bodies). There is also a strong case for the local AWB to carry out these reviews, since such bodies should be best informed in terms of project objectives and all details of the animals used, accommodation, procedures, staffing, etc.

It will be important to avoid situations whereby retrospective review is used as a means of blocking the licensing of new projects.

Training

The Directive failed to ensure consistency of training across the EU. So unless the Competent Authorities across the EU voluntarily agree common standards, we will not get over the current restrictions on mobility of research personnel between EU countries.

Licensing of trained staff allows for a record of who does what and what they are able to do in different research organisations and within an authorised, licensed project. Licensing of staff also encourages the provision of training conferences, workshops and course attendance, which can improve staff competence and raise scientific and welfare standards (e.g. the courses run by the UK Centre for the 3Rs).

Administrative cost

In the current economic climate, Member States may not be ready for the cost implications of the implementation. Researchers should encourage their relevant Ministry to carry out an impact assessment of the costs and regulatory burdens. Some costs are not easy to avoid (e.g. cage size) but others might be avoidable (e.g. number of inspections, inspectors, committee, evaluation and authorisation of projects, etc.). It is important to point out that additional bureaucracy does not lead automatically to improved animal welfare. In some countries the additional bureaucratic cost might be taken away from the national research budget and transferred to the budget of the ministry in charge of animal protection and welfare.

Administrative delays in authorisation are also of potential concern as rapid processing of applications might be prevented where there is a small, overworked bureaucracy.

Freedom of information

There are various safeguards throughout the Directive which protect confidentiality and commercially sensitive information in specific places. However, there is no all-embracing “*confidentiality clause*”. The Directive specifies only that non-technical summaries shall be published, but nothing is said about the rest of the information in project applications. EU scientists may wish to discuss with their Ministry what measures can be taken to protect confidential information, which could have security or commercial implications for institutions, scientists and animal care staff.

3. Strategic Action by EU Organisations and EU Scientists

Europe

With the help of ESF-EMRC and other pan-European groupings we can learn from experience involving other EU Directives. The European Clinical Trials Directive (EU 2001/20/EC), for example, had the laudable aim to improve the safety and efficiency of clinical trials and to provide the basis for improved European competitiveness. Unfortunately, it has had adverse effects and the implementation of the directive by individual EU member states has caused legislative differences between different nations and obstacles to the conduct of clinical trials.

ESF-EMRC recommends that a mechanism through which scientists in particular Member States can be alerted to progress on implementations, including those that are off-target to the general aims of the Directive, is rapidly put in place. ESF-EMRC and other pan-European organisations should offer their expertise to Member States and to the EC throughout the transposition process. We will be at their disposal to explain how best to deal with the terms of the Directive to promote animal welfare while minimising red tape. This could additionally help to bring rationalisation at the national level to be applied at the EU level. Besides providing support to its member organisations at a national level, ESF-EMRC will also improve links with other pan-European organisations to ensure a close synergy at the EU level. We are for example now working closely with the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Society of Laboratory Animal Veterinarians (ESLAV) and FELASA to produce a more detailed document and additional resource to complement the present paper. The aim is to further help the community during the implementation process. Finally scientists should also engage with pan-European scientific organisations that promote animal research and welfare.

National level

At the national level, EU scientists must avoid complacency: if Member States do not implement the spirit of the Directive, supporting effective and responsible research in animals, everything that has been achieved to date could be lost. Scientists must be watchful and make sure they and their representative bodies are fully engaged and consulted in the process of implementation. ESF-EMRC member organisations will be key players in this process and we will provide them with support if necessary but

the development of national coalition groups would also greatly facilitate this process.

The quality of the translation of the Directive into national language is one factor that needs particular attention. The Directive offers plenty of flexibility for implementation and this might be positive through a pro-science translation but could also lead to the risk of ‘gold-plating’ in some countries.

Scientists should encourage national ministries responsible for the Directive to keep up to date with what is happening in other Member States. New national laws will not necessarily be needed in all Member States such as the UK, France or Germany which already have laws in place. Specific areas and issues will be addressed by new text of laws depending on the country. Other countries might need completely new laws.

4. Conclusion

We are now entering a critical period for the future of animal research in Europe. Scientists must be vigilant that their governments now enact legislation that is in keeping with the more positive spirit of the Directive. That legislation should continue to allow the responsible use of animals in research for maximum scientific, medical and veterinary benefit carried out in conditions that optimise animal welfare. Scientists must therefore be ready to participate in the translation of the Directive in national legislation. In addition, they should try to participate as experts in the different committees involved and provide the EC with valuable scientific results on the development and limits of alternative methods, the upper and lower thresholds and the impact of the Directive on animal welfare and science.

In the future, ESF-EMRC will remain actively involved throughout the transposition of the Directive. We will of course provide support to scientists as well as our member organisations at a national level but we will also remain at the disposal of the EC and of those Member States that request our input.



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ISBN: 978-2-918428-33-6