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New Coalition to represent academic science on EU animals directive

The European Coalition for Biomedical Research was launched this week in Brussels to represent the interests of academic scientists in the political debate about the revision of Directive 86/609 on animal experimentation.

Thirty seven academic associations ranging from Lithuania to Portugal have formed the European Coalition for Biomedical Research, which has been set up specifically to address the revision of the EU directive on animal experimentation. Currently there are 34 associations from 17 countries in the Coalition, representing over 37,000 scientists.

EBRA is a founding member of the new Coalition. More information can be found at its web site (www.ecbr.eu).

"When it comes to lobbying within Europe, coalitions are much more effective than single associations," commented Dr Mark Matfield, "and the larger the coalition, the more effective it can be."

The Coalition has drawn up a manifesto covering all the points that it would like to see included (or excluded) in the revised directive, which they will be presenting to the European Commission. In addition, the Coalition will be helping its members inform MEPs in their respective countries about the reasons for needing to continue to use animals in medical research. Some of the previous debates on the issue have shown that there is a considerable knowledge gap which needs to be filled.

When the draft directive is published, the Coalition will scrutinise it line by line and, where there are clauses that need changing, they will seek the help of MEPs to ensure that appropriate amendments are tabled, debated and inserted. The objective is to achieve a new directive which balances the need to have animal research properly regulated with the need to allow the research to proceed without undue delays, bureaucracy or hindrances.

At the inaugural meeting, the following people were elected to serve as the Executive Group of the Coalition:

Professor Edith Olah, Chairman
Dr Mark Matfield, General Secretary
Professor Peter Janssen, Executive Member
Dr Duncan Banks, Executive Member

Professor Christine Giudicelli, Executive Member

The members of the ECBR

With 33 member associations when launched, the ECBR is inviting other European associations in the biosciences to join.

The current members of the Coalition are:

Association for the Study of Animal Behaviour
Austrian Neuroscience Association
Austrian Pharmacology Society
Belgian Society of Neuroscience
Belgian Association for Cancer Research
Biochemical Society
Brain Research Society of Finland
British Association for Psychopharmacology
British Neuroscience Association
British Pharmacological Society
Danish Soc for Pharmacology and Toxicology
Dutch Neuro Federation
Dutch Pharmacology Society
European Association for Cancer Research
European Biomedical Research Association
EBRA Italy
French Society of Pharmacology
German Neuroscience Society
German Society for Immunology
Greek Society of Pharmacology
Hellenic Society for Neuroscience
Hungarian Neuroscience Society
Hungarian Cancer Society
Italian Society of Ethology
Lithuanian Biochemical Society
Mario Negri Institute for Pharmaceutical Research
Netherlands Society for Behavioural Biology
Physiology Society
Polish Society for Endocrinology
Portuguese Society for Neuroscience
Scandinavian Physiology Society
Slovak Physiological Society
Slovenian Biochemical Society
Society for General Microbiology

The ECBR Manifesto

The Manifesto setting out the position of the ECBR on the revision of Directive 86/609 was agreed at the inaugural meeting and is set out below.

This manifesto has been written before the draft revised directive has been published and should, therefore, be regarded as a preliminary version. It will be amended and extended in the light of the specific proposals contained in the draft directive.

This manifesto is based upon the wording in the existing Directive 86/609 and the proposals discussed in the expert version of the public consultation on the revisions released in June 2006 on the European Commission web site.

We welcome and support many of these proposals, remain neutral on some and have concerns about a limited number of them.
We are also concerned about the omission of proposals to address some known problems with current regulatory systems. This manifesto discusses the changes we would like to see in the wording of the existing

directive, our concerns about the proposals (or absence of suitable proposals) in the expert consultation and how we consider that they should be changed. By these changes, we seek to achieve an effective system of regulating animal experimentation that balances the need to conduct research and development in the biological and medical sciences.

Recitals

The recitals are statements at the beginning of a directive (typically, phrased as "Whereas…." or "Having regard to …") that state the important background considerations. They do not apply as legislation but are used to interpret the actual clauses of the directive when clarification is needed.

1. ECBR considers that there should be a recital stating the importance of the freedom of research for scientific inquiry. It should be noted that the Article II-73 of the proposed European Constitution stated that this freedom shall be respected. Using the wording of this clause as a model, the following new recital is proposed: "Whereas scientific freedom of research shall be respected."

Purpose of the Directive

The purpose of the existing directive as stated in clause 1, is "to ensure that where animals are used for experimental or other scientific purposes the provisions laid down by law, regulation or administrative provisions in the Member States for their protection are approximated …."

2. ECBR strongly supports the harmonisation of national controls on animal experimentation across the EU and is concerned that the wording of this very important clause is too weak. Accordingly, it is proposed that the equivalent clause in the revised directive should focus on harmonisation and use this term instead of the weaker "approximated".

Harmonisation

Since the objective of the revised directive is to harmonise the systems of regulating animal experimentation across the Member States, it is surprising that the existing directive contains a clause (article 24) which specifically states that Member States may adopt stricter regulatory measures if they so wish. Whilst it is true that Member States have this right under any Directive, ECBR considers that it is unwise and unhelpful to include a clause that specifically makes mention of it and encourages Member States to do so.

3. ECBR proposes that the existing article 24 should be deleted and replaced with an article encouraging Member States to harmonise their systems of regulation by adopting a system as close as possible to the one set out in the revised directive.

Animals killed to provide tissue

The expert consultation proposed that the revised directive should cover: "… animals bred for the primary purpose of their tissue and organs to be used in experiments or other scientific purposes with an exemption for authorisation if euthanasia is performed by competent person using a method appropriate to the species."

ECBR considers that the inclusion of animals killed to provide tissues or organs would add a significant extra administrative burden for little animal welfare benefits. Current practice is to use animals killed as surplus breeding stock to provide such tissues or organs and these animals already have to be killed by a humane method. However, with the proposed exemption "for authorisation if euthanasia is performed by competent person using a method appropriate to the species" this additional burden would be removed (because all such euthanasia is already done this way). This obviously raises the question why bother with this item of regulation at all. It would be far simpler, and achieve a greater animal welfare benefit, with minimal extra administrative burden, to include a requirement that all animals bred for research should be killed by a competent person using an approved humane method appropriate to the species".

4. ECBR proposes that animals bred to provide tissue or organs should not be included within the scope of the revised directive. However, there should be a requirement that all animals bred for research should be killed by a competent person using an approved humane method appropriate to the species.

Euthanasia

The expert consultation proposes a ban on the use of CO2 for euthanasia. However, there is still a debate about this technique. A recent expert workshop concluded that there is no practical alternative that could be said to be more humane. Moreover, it appears peculiar to use international legislation to ban one specific technique amongst many, rather than to set a system to decide which techniques should be approved as humane.

5. ECBR proposes that there should be no ban on the use of CO2 euthanasia in the revised directive, but that the Commission should be charged with calling together an Expert Group to determine which methods of euthanasia should be approved as humane.

Authorisation

The expert consultation proposed that the authorisation system for projects should have three basic components:

i) A compliance check to ensure that the necessary authorisations are in place: i.e. for the individuals and institution, inspection reports show compliance, statistical reporting completed, etc,
ii) A supporting opinion from a detailed local ethical evaluation, and
iii) A deadline by which the authorising body is required to respond.

This authorisation system relies on local ethical evaluation to assess the justification for the project, numbers and species of animals, experimental procedures, implementation of the three R's, husbandry and housing, humane end points, etc.

ECBR supports this proposed system of authorisation and ethical review, but has serious concerns about two aspects of it.
Firstly, the requirement that the authorising body should respond by a certain deadline is far too weak. A response could include any type of communication, including a confirmation that the application for authorisation is under consideration. Moreover, the deadline should apply to the whole process of ethical review and authorisation and the deadline should be 60 days, as used in the clinical trials directive.

6. ECBR proposes that the authorisation process should require the authorising body to make a definitive response by a deadline, which should be specified in the revised directive and that the deadline should apply to both local ethical review and authorisation. It is proposed that the deadline should be 60 days from submission of an application to local ethical review.

Secondly, we are seriously concerned that there will be needless and inefficient duplication with the authorisation processes in a number of Member States. These are the countries that currently have a system involving a central or regional authority assessing all those aspects that are proposed to be the task of the local ethical review. It is most unlikely that, when the new directive comes to be implemented in such countries, these authorities will hand over their decision-making powers to local ethical processes. Instead, it is more likely that they will duplicate the assessments made by the ethical review as part of the authorisation process. This will result in unnecessary duplication of work, additional costs and delays to authorisations.

7. ECBR proposes that the revised directive should specifically state that the authorisation system in each Member State must not duplicate any of the assessments of projects made by the ethical review process.

ETS123 caging and welfare standards

The caging and welfare standards for laboratory animals set out in the Council of Europe Convention ETS123 have recently been revised. Since the EU has ratified this Convention, they are legally obliged to implement these standards in the revised directive. The only question is how long will the new directive allow for institutions to achieve compliance.

The new ETS123 standards are significantly higher than the old ones and many Member States, particularly the newer members of the EU, will be required to make a substantial investment in new buildings, equipment and staffing to comply with them. It has been estimated that the total cost of complying with these new regulations across the EU will be in excess of one billion Euros.

This will create particular problems for the academic sector, where experience has demonstrated that governments do not easily provide the capital or recurrent funding to meet such new regulatory standards. Academic institutions are often required to argue their case, sometimes for years, before such funding is made available. Even then, it takes several more years before the necessary new animal facilities can be constructed and are ready for use.

8. ECBR proposes that the revised directive should allow a period of 10 years after the date of implementation within the Member State, for institutions to be required to comply with the ETS123 standards.

Transparency

The expert consultation proposes that all relevant, non-confidential information from project authorisations and ethical review should be made public. We agree that there should be greater transparency about animal experimentation, because it would improve the public understanding of why animals are used in research and the welfare standards that are applied. However, this proposal would create an enormous administrative burden and only increase transparency by a limited amount.

In most EU countries, the law defines 'confidential' in such a way that the majority of the information in project authorisations and ethical reviews would be included under that definition. Moreover, experience has found that the amount of work involved, and the level of technical and legal expertise required to remove the confidential information from the documentation involved is greater than that required to make the applications in the first place.

A far better system of routinely publishing anonymous summaries of the projects given authorisation is already in use in one country where it has been found to involve little extra administrative burden and to add greatly to transparency.

9. ECBR proposes that the suggestion that all relevant, non-confidential information from project authorisations and ethical review should be made public should be replaced with a requirement to publish anonymous summaries of all projects given authorisation.

Non-human primates

The expert consultation proposed that, after a phase-in period, there should be a ban on the use of first generation (F1) purpose-bred non-human primates (NHPs). This proposal was based on highly inaccurate information which suggested that the vast majority of NHPs used in EU research were F2. In fact only new-world primates, which constitute only 13% of all NHPs, are F2. The remaining 87% are old-world primates of which virtually none are F2. There is presently no supply of these animals for research and experts in the field agree that there is not likely to be any such supply in the foreseeable future.

The idea that using F2 NHPs is better animal welfare is a matter of debate rather than being widely accepted amongst primate experts. However, it is widely accepted that the standards at breeding centres have a significant effect on the welfare of these animals. It would be far more effective to limit the use of NHPs to those supplied by the better breeding centres. This would require a system of inspecting and approving the breeding centres out side the EU. Some Member States already operate such a system. This system could also be used to apply conservation criteria to the supply of NHPs from specific regions or countries.

10. ECBR proposes that there should be no ban on using F1 NHPs in the revised directive, but that there should be a ban on using NHPs from breeders that have not been inspected and approved and a requirement that a system of inspection and approval should be set up.

Multiple site approval

Some research projects operate at more than one institution. These include collaborative projects and cases where a researcher is based at one institution but needs to use specialist animal facilities that are only available at another institution. In some Member States, the national legislation required such projects to have passed local ethical evaluation at both sites. This obviously involves needless duplication and can create serious problems if the two ethical evaluation processes require incompatible modifications of the proposed research.

11. ECBR proposes that, for projects that will operate at more than one institution, the ethical approval of any one of these institutions must be accepted by the other institutions involved.

Training

Although the expert consultation discussed training, it only made a very limited proposal to specify some ‘key elements’ of training.
It would be extremely useful to have mutual recognition of training between Member States as this would facilitate the movement of scientists and technicians and the flow of scientific expertise within the EU. Moreover, the expert consultation recognises the desirability of such mutual recognition, but does nothing to seek to achieve it. However, it would be relatively simple to create an expert body to agree on training standards across the EU, which could then be mutually recognised between Member States.

12. ECBR proposes that the revised directive should charge the Commission with setting up an Expert Group on training, to define the training standards and curricula for the EU. The revised directive should require Member States to adopt these standards and curricula and have mutual recognition of them.

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