EBRA Bulletin

Produced by the European Biomedical Research Association

June 2009

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CONTACT INFO

tel

email matfield@ebra.org

postal address
25 Shaftesbury Avenue
London W1D 7EG
United Kingdom

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Parliament adopts Parish report

The European Parliament has adopted a report proposing a number of significant improvements to the new directive on animal research.

In December 2008, the proposed new directive on animal research was sent to the European Parliament. It managed to complete its first reading in parliament shortly before the end of the session and the June elections.
As reported in the last edition of the EBRA Bulletin, the proposal for the new directive was assigned to the parliament's Agriculture Committee and Mr Neil Parish was appointed as rapporteur.
On 16th February the Agriculture Committee invited a number of experts, including a representative of the European Coalition for Biomedical Research, to give evidence about the new directive and how the parliament should seek to amend it. Throughout this period ECBR was actively lobbying the rapporteur and other members of the Agriculture Committee to have a number of specific amendments proposed. We received the support of a number of MEPs and all the amendments we were seeking were proposed for debate.
The parliamentary procedure is complex, involving two other committees (Research and Environment) with all members able to propose amendments. Overall, more than 750 amendments were proposed for debate. Following the three committee votes, the rapporteur Neil Parish was left with 161 amendments in the report which was forwarded to the plenary session of the full parliament in Strasbourg on 4th May. The report was adopted by a substantial majority with 540 votes in favour to 66 against.
The full set of amendments adopted can be found at:
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0343

The changes proposed by parliament

Many of the amendments proposed by the European Parliament will be welcomed by the research community.

The main amendments that the parliament is calling for are summarised below.
1. Excluding embryonic or foetal forms of non-mamalian animals from the scope of the directive.
2. Allowing more humane methods of euthanasia, even if they are not on the approved list in Annexe V of the directive.
3. Removing the limitation of primate research to studies "undertaken with a view to the avoidance, prevention, diagnosis or treatment of life-threatening or debilitating clinical conditions in human beings."
4. Changing the requirement to use second-generation (ie F2) captive-bred primates to a requirement to use primates from self-sustaining colonies, but only after the feasibility of this has been established.

5. Adding an annexe defining the severity of procedures.
6. Changing the severity limit for re-use from mild to moderate.
7. Mutual recognition of qualifications to conduct animal procedures between Member States.
8. Annual review of projects to be limited to those classed as severe or using non-human primates.
9. Inspections to be once a year on average, not twice a year.
10. Projects classified as mild to only need approval of the local ethical review body and then to be notified to the national authority.
11. Retrospective assessments limited to projects involving severe procedures.
12. Non-technical summaries (which are to be made public) to be anonymous.
13. Project authorisations to last for 5 years (not 4 years).
14. Amendments to mild or moderate procedure, which do not increase the severity, to be authorised by the local ethical review body.

Parliament has also proposed a lot of amendments which tidy up clauses and make minor improvements. However, there were also a few amendments proposed which seem impracticable and one or two that would be unreasonable. These include requiring the European Commission to review the progress in developing alternatives to the use of primates in research every two years, requiring each establishment to have one trained animal welfare person available at all times and unrealistic provisions on data sharing and checking.

There are still quite a few stages left in the legislative process and we are confident that most, if not all, of the remaining problems with the proposed text and amendments can be resolved. We should also be aware that we cannot expect all the amendments we like to be incorporated into the final version.

What happens next?

The proposed directive is still in the first reading stage, but now it is the turn of the European Council.

We understand that the European Commission will soon produce an amended version of its proposed text for the new directive, in which it will incorporate some of the amendments proposed by the parliament.

Now that the first reading in parliament has been completed, the proposal for a new directive has its first reading in the European Council. This is the body composed of representatives of the member states. They will consider the Commission's amended text and the amendments proposed in the parliament's report. In due course the Council will produce its own report (called a common position) indicating which amendments it supports and any further changes it wants to see in the text of the directive.

The Council itself is composed of the relevant government ministers from all members states - in this case the agriculture ministers. However, the role of the Council is normally limited to the formal adoption of the common position. All the real work is done by a working party of government officials and COREPER - the committee of permanent representatives of the members states.

Sweden took over the presidency of the European Council on 1st June and they have indicated their intention to give this directive a speedy first reading. Working party meetings have been scheduled through July and September, with COREPER due to consider it in September. The presidency is aiming for the common position to be adopted at the November meeting of the Council.

Once the Council has produced its common position, the European Parliament starts its second reading. This is limited to 3 months (witrh a possible 1 month extension). Normally, there are no new amendments proposed at this stage. Instead, the parliament considers which of its original amendments it really wants to keep, in the light of the Commission's amended proposal and the Council's common position. However, a new parliament will have been elected between the first and second readings, so there is a possibility that new amendments could be accepted.

What the scientific community can do next

Scientific associations in member states can influence this stage in the process.

The lobbying by the academic associations within ECBR and individual scientists across the EU was very effective duing the first reading in parliament.

The opportunities for influencing the first reading in Council are more limited. Unlike the parliament, which is intended to represent the citizens of Europe, the Council represents the governments of the member states. This means there is no real avenue for individual lobbying by scientists at this stage of the process.

However, scientific associations within Europe can contact the relevant government official to express their views about the directive and the amendments that have been proposed. We will be contacting the national associations within ECBR to advise them how this can be done.