

Brussels' threat to EU and UK law on animal experiments



The UK's legal requirement to use alternatives to animal experiments where they are 'reasonably and practicably available', is under serious threat because of proposed changes to EU legislation, the Dr Hadwen Trust for Humane Research has today revealed.

The new proposals by the EU Presidency have emerged as part of ongoing negotiations to revise the 20-year old EU Directive 86/609 on animal experiments. The current EU Directive, which is implemented across all 27 member states including the UK, contains key wording (Article 7.2) making it compulsory to use non-animal research methods that are "reasonably and practicably available" instead of experimenting on live animals.

The new Presidency proposal would, if adopted:

1. **reduce the mandatory nature of the 'alternatives clause'**: in the current EU Directive, it is mandatory for member states to use non-animal alternative methods if they are available. Article 4.1 in the Presidency's draft text downgrades the mandatory nature of the requirement, to simply require that this is done "wherever possible". This is a subtle but highly significant change in the legislative language that would allow member states far more freedom to ignore or delay implementation of alternatives.
2. **allow member states to delay implementing alternative test methods until they are 'recognised by Community legislation'** – an administrative process that can take years: Article 7.2 of the existing Directive clearly says: *"An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available."* The new proposal deletes this wording completely and states instead that an alternative must be used only once it has been "recognised by Community legislation" (Article 13.1). This means that member states would no longer be required to implement alternatives as soon as they have been scientifically validated but instead would have to wait for the test to go through the lengthy administrative process needed to achieve adoption into the EU regulatory framework. This could potentially add years to the time it takes to replace animal tests with alternatives.
3. **limit the scope of the 'alternatives clause'** so that it no longer requires application of alternatives to all procedures, most notably those carried out for the purpose of basic medical research where the vast majority of animals are used: only alternatives

to toxicological and 'safety' tests are recognised by Community legislation but toxicological tests account for only around 10% of all animal use. So for the rest, mainly procedures used in basic medical research, the legal requirement to use available alternatives to animal procedures would simply no longer apply.

- 4. result in member states such as the UK having to weaken national legislation on alternatives:** Article 2.7 in the Presidency proposal also removes a member state's ability to maintain higher standards or introduce stronger standards in any area other than "care and accommodation". That means that Britain could be forced to weaken its national legislation – the Animals (Scientific Procedures) Act 1986 – to the lowest common denominator level, removing the legal requirement for alternative methods to be used.

The Presidency draft text is currently under discussion and is expected to be finalised at EU Council level within the next few days. Unless MEPs protest against the changes in time, there is a real danger that the 'available alternatives' wording that has been applied through EU law since 1986 will be lost.

"For decades the cornerstone of British and EU animal research law has been that if a non-animal alternative test method is available, the animal test must not be performed. It's a common-sense clause vital to ensuring that science utilises the most modern techniques and animals are protected against excessive use." explains Wendy Higgins of the Dr Hadwen Trust for Humane Research. *"The EU should be leading the world in promoting humane research, and the 'alternatives clause' is central to that. It would be grossly irresponsible for EU politicians to consider such a morally and scientifically retrograde step as removing this wording now."*

The Dr Hadwen Trust, one of the leading organisations working to update and improve Directive 86/609, is calling for an EU-wide strategy to vastly increase investment in new non-animal replacement methods. The charity funds medical research at British universities to develop new non-animal techniques to replace live animals, such as 3-D models of disease, advanced human brain imaging techniques and computer modelling.

The charity has written to Members of the European Parliament asking them to reject deletion of the 'available alternatives' wording and the proposal to stop the UK from introducing stricter animal protection measures than those required by the new EU law. The speed and secrecy of the legislative process underway is a major concern. Rather than holding a conventional second reading in the European Parliament, MEPs and the Presidency have agreed to a truncated process which bypasses full debate.

Says Wendy Higgins:

"It is possible, if not likely, that UK MEPs are not even aware that plans to weaken the alternatives clause are being discussed, which is why we need to raise the issue with them directly. We are calling on UK MEPs to reject these changes and uphold the law on humane research."

The European Commission published its proposal to revise Directive 86/609 EEC in November 2008, and the European Parliament adopted its first reading position in May this year. Member State experts concluded discussions during the autumn, and the Presidency draft is now being debated through controversial 'trialogue' discussions between the Commission, Parliament and Presidency. Triilogue discussions are notoriously undemocratic; the draft document commented on in this release is not publicly available and is, contrary to expectations regarding openness and accountability of EU institutions, withheld from public scrutiny. A new draft is expected to be finalised by Council representatives on 19th November, with the Parliament having had very little input.

It is expected that the Council and the Parliament will reach agreement before the end of this year but if agreement is not reached, the Parliament will hold a full second reading debate during 2010.

Notes:

¹ The existing EU law is Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.

² Proposals to revise Directive 86/609/EEC were published by the European Commission in November 2008 – the Commission's proposals can be read [here](#).

³ The new proposals by the Council of Ministers are contained in a document called, Note from the Presidency to the Working Party of Agricultural Counsellors / Attaches 14825/09 dated 28 October 2009.

⁴ The UK Animals (Scientific Procedures) Act 1986 can be found [here](#).

⁵ 12.1 million animals were used in EU experiments in 2005; Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union published 5/11/2007 (these are the most recent EU wide statistics available).