

Briefing – Regular Thematic Review

Proposal for a Directive on the protection of animals used for scientific purposes (revising Directive 86/609/EEC)

Background

The replacement of the use of animals in research and testing is a complex issue. Requirements for replacement in regulatory tests for example, are different from those for academic, or fundamental research.

The concept of a biannual thematic review of areas of animal research and the availability of alternatives and how these might be implemented (specifically for primate use under article 8 and to broadly review any areas of research under article 53) achieved strong support in the Committee stages and was adopted (ams 59 & 194) by the European Parliament with the Commission singling the concept out for praise during the plenary session.

Rather than address such wide-ranging and complex issues all together during review of the whole Directive, a framework for thematic reviews must be established to allow the Commission and stakeholders to review the use of specific species in specific areas of research and testing, on a case-by-case basis.

Detailed research and assessments can be applied to:

- The use of specific species in specified fields of research and the opportunities for replacement
- Validation and implementation of alternative methods as they become available.
- Retrospective and systematic reviews to inform future cost/benefit analysis.
- Statistics, reporting and data sharing
- Species within the scope of the directive, to incorporate new knowledge
- Genetically modified animals; welfare and validity
- Cost-benefit assessments and pain severity bands
- Methodology and best practice
- Other developments in scientific and animal welfare knowledge

Consultations with stakeholders could identify and set objectives, targets and timetables to replace animals or amend regulations, appropriate to the need as well as identify areas where replacement could be most rapid. Different frameworks should also be set for regulatory testing, which is standardised, and academic research, which is varied in nature.

Key objectives for each review would include:

- Research, consultation, assessment of current position
- Identifying scope for change
- Establish need for development or implementation of new methods; set timetables or targets as appropriate to the case.

The regularity of the review (biannual) is key to the success of the process, allowing it to focus on areas with a clear opportunity to replace animal experiments enabling a selective process rather than attempting to address all issues at once. A clear timetable will enable stakeholders to make the most effective input.

The current revision, which has seen not a single area of experimentation replaced, has shown that trying to address all of the issues concerning animal experiments at once AND seek areas

to replace is simply not viable. Ad hoc opportunities to review and target replacement will lack focus and be overwhelmed by the number of areas to be considered. It is vital that a clear course is set to allow regular and measured consideration of replacements.

Our views on the present positions indicated by the different institutions are outlined below:

European Parliament

European Parliament Amendment 59, on the review of primate use every two years, is very important to ensure specific protection is given to non-human primates. It is important the Parliament indicates their support towards the development of alternative methods where possible and timescales for reviewing primate use.

This is not a controversial amendment but a practical and proportionate approach to the replacement of primates in experiments. The review ensures a special focus on primates, an area of particular concern, in tandem with the broader remit of the review under Article 53.

This cautiously addresses the call in Written Declaration 40/2007 for a timetable to replace primate experiments and acknowledges that primate use is an area of special concern requiring focused consideration.

European Parliament Amendment 194 as regards to the addition of the thematic review is very strongly supported, in particular because it provides opportunities to for identification of areas where the implementation of replacement methods can be accelerated. We believe that the over-arching principle should be to seek areas where the implementation of replacements can be accelerated.

Council

It is very disappointing that in the draft text presented by the Presidency the review of primate experiments under article 8 has been dropped, and the requirement to conduct regular reviews under article 53 has also been omitted. Two very practical and proportionate measures have been swept aside.

Parliament's amendments to Article 53 (a) and Article 8.2(a) are not adequately covered in other sections of the text as stated by Council and should therefore be reinstated to indicate commitment of EU towards animal welfare and alternative methods.

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