

86/609: News from co-decision

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The Council

The adoption of the Parish report by an overwhelming majority of MEPs (80%) in May 09 was only a very first step in the co-decision process. The Council is now looking into the text and would propose its own amendments. Ultimately, the Council will try and reconcile its proposed amendments and those from the European Parliament to allow for a smooth progress in further steps of the procedure. But it may well be that the two positions might not be completely compatible.

The Council working group on animal welfare will hold its next meetings on 22 and 23 July. The group will have a first exchange of views on the draft common position prepared by the Swedish Presidency. Further meetings will take place in September and in October. The Swedish Presidency aims at adopting a Council Common position at the 19 November Agriculture Council.

As far as we understand from the contacts with different member states (based on feedback from PAT members and the Brussels coordination group) the following questions have been raised to date in meetings under the Czech Presidency:

- excessive bureaucratic burden, and possibilities to maintain existing systems in place
- severity classification to be established asap
- need to clarify on the roles and tasks of different ethical review and authorisation bodies,
- reasons for including invertebrates; animals used in training and for tissue collection
- the F2 requirement was questioned,
- limitations of the use of primates to certain essential uses is supported, but not necessarily to extent proposed by the Commission
- concerns were raised about national reference laboratories in particular on their funding remit
- Reuse would be further looked at to find adequate balance between reduction and refinement (a case by case approach was suggested)
- Annexes on euthanasia and on housing and care would be further debated.

Not all Member States have already developed their positions. Some of them are only consulting now with different stakeholders groups. In the UK, the House of Lords is conducting an inquiry with a series of hearings. They expressed interest in meeting an EFPIA delegation and this meeting will take place on 14 July 2009.

The Commission

Usually within a few weeks from an EP vote, the Commission prepares an amended proposal where their incorporate EP amendments which the Commission can support (as they are in the spirit of the text or improve the text). However, for this dossier, no amended proposal is planned and the Commission will most likely inform the Council on their opinion almost at last moment before the vote.

In the meantime, the Commission set up an expert working group on severity classification that will complement the EP amendment on Annex VIIa (proposed definitions and examples of procedures under each severity class). The meeting will take place in Brussels on 9 and 10 July. The Commission invited all key stakeholders groups, including trade associations representing different industry sectors, professional and scientific organisations such as ESLAV or FELASA, animal protection groups, one patient organisation and all member states.

The Commission wants to maintain the four classes currently in the proposed revision: non-recovery, up to mild, moderate and severe. They also want to establish upper limit of severity beyond which no study should be conducted, as well as lowest levels of severity where the administrative procedure of the directive should not apply.

The European Parliament

What would happen with the revision of 86/609 after election? Strictly following the rules, according to the new Rules of Procedures of the Parliament there are several theoretical options for "renewed referral to Parliament" of a text on which the EP has already given its opinion.

One of these is that “if the conference of presidents consider it desirable” – the Commission could be asked to refer again its proposal to the EP (to restart the process again). This is highly unlikely. However the question remains – how determined the new parliament would be to defend a position taken by the old parliament.

Obviously, the bioscience sectors should start again a targeted information campaign to avoid leaving the field to our opponents and take the risk of losing support for the key first reading achievements.

Even in case where the first reading position is not questioned by the new parliament, the rules for admissibility of amendments can be changed – a new political situation may make it possible to

table amendments which have not been adopted in the first reading (which is the general rule).

Co-decision for non specialists

As recommended by PAT animal welfare in May 2009, EFPIA prepared a lay language overview of the co-decision process focussing on key players and milestones for the revision of 86/609. This document can be used to inform of academic organisations and third parties not familiar with the EU procedures and in particular raise awareness about the fact that the EP first reading vote in May is just one milestone in the overall co-decision procedure.

Read more: DocShare

OIE guidance on animals used in research

The World Organisation for Animal Health is currently revising its Code for Terrestrial Animals. At a meeting of dedicated committee on animal welfare, the issue of welfare of animals used in research was discussed and as a result a draft document on the Use of Animals in Research, Testing or Teaching was produced and released for comments (the deadline for comments is just about to expire).

In the preamble, the OIE recognises the vital role played by the use of live animals in research and the contribution of such research to wellbeing of people and animals. The OIE highlights the need for humane treatment of sentient animals and that good quality of science depends upon good animal welfare. Finally the OIE emphasises the importance of standards based on outcomes for the animal.

While the document is supposed to set guiding principle, the OIE considers that the oversight of animal research should be implemented in each country, recognising that the systems would vary according to cultural, economic, religious and social factors.

The document provides for a set of definitions. The scope covers all animals used in research, teaching or testing, as well as animals bred for tissue collection.

Guidance is provided as to the oversight framework, specifying that its key elements are: project proposal review, facility inspection and animal care and use programme review. The components of each of these three key elements are defined, without specifying at what level and by which body it is to be conducted. The necessary expertise is however defined.

The document contains a rather detailed description of what is meant by assurance of training and competency. Other chapters include: provision of veterinary care; physical facility and environmental conditions; source of animals; husbandry; occupational health and safety; and post-approval monitoring.

This document could ultimately contribute to global convergence of standards. The approach focused on outputs rather than processes, could be used in advocacy on the revision of Directive 86/609.

We will monitor further developments on this guidance.

The draft text is available at: http://www.aphis.usda.gov/import_export/animals/oie/downloads/tahc_mar09/tahc_mar09.pdf

EU qualitative study on image of science

The Commission DG Research and DG Communication commissioned a survey on the image of science and the research policy of the European Union. The outcomes of the study conducted among the citizens of the 27 member states were published in October 2008. The commission surveyed EU citizens attitude vis à vis stem cells research ... and experiments on animals.

On this latter, quoting from the report:

- "Attitude regarding experiments on animals show themselves to be extremely homogenous in all the groups questioned"
- The survey identified "more or less strong emotive reactions of compassion towards animals (amongst female respondents in particular) counterbalanced by the rational consideration of the practical

impossibility of getting by without tests (unless they were to be performed on humans themselves)

Areas that give rise to interest include the medico-pharmaceutical field, amongst others. As to the channels and sources of information about science, television comes first followed by written press. Internet is often mentioned as source for finding more detailed information about something to which attention has already been drawn by other channels.

The full report is available at: http://ec.europa.eu/research/science-society/document_library/pdf_06/qualitative-study-rapport08012009_en.pdf

Events – mark your diary

VII World Congress on Alternatives 30/08- 3/09, Rome

The 7th World Congress on alternatives and animal use in the life sciences will take place in Rome, Italy from 30 August to 3 September 2009. The congress was given the motto "Calling on Science" in order to emphasize that scientific progress today goes hand in hand with progress towards the reduction, refinement and replacement of experimental animals (the 3-R's). Programme, additional information and registration is available at: <http://www.aimgroup.eu/2009/wc7/index.html>

NC3Rs Primate Welfare Meeting 28/10/09, London

This event, which is combined with the European Primate Veterinarians will be held in London on 28 October 2009. The theme of this joint NC3Rs/EPV joint session is "Refining scientific procedures". The meeting is free and open to laboratory personnel working directly with primates used in research. For more information and registration (deadline 30 September) visit: <http://www.nc3rs.org.uk/event.asp?id=1038>

EPAA Annual Conference 6/11/2009, Brussels

The 2009 Annual Conference will take place on 6 November in Brussels. This year event will be dedicated to dissemination of 3Rs information, the mechanisms of dissemination and its role in enhancing regulatory acceptance; speeding up uptake of 3Rs methods in labs; and raising the profile and legitimacy of 3Rs research. More information and on line registration would soon be available at www.epaa.eu.com

NB. Calendar of EU institution meetings and other events related to the revision of Directive 86/609 is available on DocShare.

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