Terms of Reference

FELASA/ ECLAM*/ ESLAV** working group:
Reporting the Severity of Procedures Retrospectively

Background

The revised Directive 86/609 contains a requirement that Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures (Article 49.2). This new information will be needed three years after transposition. Two countries in Europe, the Netherlands and Switzerland, currently collect such information but there is no experience in the remainder of countries. The UK Laboratory Animal Science Association (LASA), in collaboration with Home Office Animal Procedures Committee (APC), has undertaken a study to assess the feasibility of reporting data on the severity of scientific procedures on animals. Its report was published in 2008 and can be found at http://www.lasa.co.uk/LASA%20APC%20severity%20project.pdf. This report makes recommendations for a scheme which is similar to that in Switzerland. A number of pilot trials are underway in UK establishments to assess the ease of operation of the proposed scheme and the impact on resources.

Issues

Collecting and reporting data on the outcome of animal procedures is a new concept to the majority of animal users in Europe. Before this statistical information can be submitted to the EU Commission there are a number of decisions to be made. For example, is the system being trialed in the UK acceptable to the rest of Europe? Are there any other approaches that may simplify the process? Could a phased or stratified approach be considered? How are the new data to be incorporated into the annual statistics? How can the benefits of using animals be linked to the harms which will become apparent in the new statistics? The LASA working group has considered these questions but a European view is now needed. The Commission (DG Environment), has undertaken to initiate a working group to establish a common format for submitting this new statistical information and has indicated it would use the LASA scheme in its deliberations. The Commission will have 18 months from adoption of the Directive to complete this work. FELASA believes that the outcome of its own working group could inform the Commission’s proposals going forward.

Tasks

The working group should appraise the LASA/APC report before deciding on the final scope of its work. Below are some initial suggestions of work for consideration:

1. Appraise the options for reporting the severity of procedures retrospectively. Confirm the suitability of the LASA/APC scheme or propose an alternative.
2. Develop detailed guidance on the operation of a retrospective severity scheme including a catalogue of worked examples covering the full range of species and a
3. Obtain feedback on existing schemes and the UK pilot schemes and consider if additional studies are required.
4. Consider mechanisms for the incorporation into the annual statistics, information on the benefits of using animals to balance the harms (numbers of mild, moderate, and severe procedures) which will be publicly available for the first time.
5. Maintain dialogue with the Commission and offer input into their statistical working group.

Dependencies

The working group should collaborate with the FELASA working group providing guidance on the severity classification of procedures as there is a level of overlap (glossary of worked examples). Contact should be made with DG Environment as they will be initiating a statistical working group to define the information to be collected and reported, including the actual severity of animal procedures.

Composition of working group

A working group of 6 to 7 permanent members from FELASA constituent organizations should be formed. It would be beneficial if Competent Authorities were represented as they will ultimately be the recipients of this new information. Input from the existing LASA working group would be beneficial and link to the ongoing pilot trials in the UK.

Budget

Budget 10 to 15,000 Euros for meetings/travel and telephone conferences

Reporting

Draft report to FELASA Board in 12 to 15 months. The shorter time-line is necessary to fit in with the time scale of the Commission’s statistical working group. Consider publication in Laboratory Animals or peer reviewed journal.

DS
30.03.10

* ECLAM – European College of Laboratory Animal Medicine
** ESLAV – European Society for Laboratory Animal Veterinarians