Terms of Reference

FELASA/ ECLAM*/ ESLAV** working group:
Severity Classification of Procedures – Guidance on implementation of the process

Background
The revised Directive 86/609 contains a requirement that all procedures should be classified as `non-recovery`, `mild`, `moderate`, or `severe` on a case by case basis using the assignment criteria set out in Annex IX (Article 15.1). Furthermore, subject to the safeguard clause in Article 50(1A), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated. Annex IX defines the severity categories, gives guidance on assignment criteria and gives examples of different types of procedure in each of the categories.

Issues
Classification of procedures is a new concept for a number of Member States and additional guidance could be invaluable to aid interpretation of Annex IX which is essential for the implementation of Article 15. Consistency of assignment of severity category across Member States is a key requirement, particularly if the safeguard clause is to be invoked. The examples given in Annex IX are limited in number and have little descriptive power to aid assignment. Additionally, the examples given relate to the procedure and do not attempt to assess the outcome such as adverse effects that may occur. A further area of potential concern is that related to animal models of pain. It is possible for the same model to be categorized across at least two bands depending on the refinement of the procedure. In addition to the application of early end-points, the degree of amelioration of pain, distress and suffering is a major factor. Further worked examples, particularly within the severe category, together with guidance on appropriate methods of applying amelioration would ensure dissemination of best practice.

Tasks
The working group should appraise the text of Annex IX and consider the content of the report from the “Expert working group on severity classification of scientific procedures performed on animals” (DG Environment July 2009) before deciding on the final scope of its work. Below are some initial suggestions of work for consideration:

1. Provide general guidance on application of proposed severity classifications of procedures to be included in project authorizations (Annex VII). The classifications will be prospective and set a limit of severity.
2. Provide further examples of procedures across all three categories. Focus on those on the cusp of mild/moderate and moderate/severe categories.
3. Expand the examples of procedures to include more descriptive power eg assignment criteria in Annex IX, Section II. Include some procedures where re-use is a feature.
4. Include guidance on severity associated with adverse clinical effects (refer to FELASA working group on the reporting of clinical signs). Consider generic approach applied specifically to species.

5. Provide examples of animal models of pain (some are available from UK Home Office).

6. Provide guidance on methods of refining procedures to ameliorate pain, particularly focused on severe procedures that may become long-lasting.

Dependencies

The working group should collaborate with the FELASA working group providing guidance on the implementation of retrospective reporting of severity as there is a level of overlap (glossary of worked examples). Contact should be made with DG Environment as they have been involved in the initial drafting of the Directive requirements.

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 have considerable expertise in this area. It may be necessary to co-opt specialists with expertise in pain recognition as well as in pain amelioration during the course of the project.

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 transposition of the Directive into national legislation. 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