

Short report on the European Commission Working group to develop Severity Classification Criteria (Brussels, July 9-10, 2009) for ESLAV AND ECLAM A-D Degryse

Under the proposed revision of Directive 86/609/EEC, the new element that appeared is the proposal to introduce an EU wide severity classification of scientific procedures performed on animals, based upon 4 classes: non-recovery, up to mild, moderate and severe.

To that end, the European Commission organized a meeting of Experts. Forty experts, representing either organisations or Members States met in Brussels on July 9-10, 2009.

Both ECLAM and ESLAV were invited and other members of either organisations present were: Anne-Dominique Degryse (ESLAV), Paul Flecknell (ECVAA), Rüdiger Hack (EFPIA), Ignacio Alvarez Gomez de Segura (ECLAM), Harry Van Herck (AAALAC Intl.), Torgny Jeneskog (Sweden), Hans Hedrich (EBRA);

Eddy Rommel (Belgium), Dag Marcus Eide (Norway), Grete Oostergard (Denmark), Kai Okva (Estonia), Peter Nowlan (Moderator)

The objectives of the meeting were to

1. develop general criteria when determining severity (duration, intensity, frequency of intervention, deprivation of ethological needs) of a procedure
2. determine a lower threshold below which the Directive should not apply, and an upper threshold beyond which animal use should not be allowed
3. prepare a set of samples for each category
4. determine retrospective assessment
5. determine whether the method of assessment should be linked to a single animal or an 'average' animal

It was stated upfront by the Commission that a lower threshold (below which the Directive should not apply) and an upper threshold (beyond which no animal use should be allowed) had also to be defined.

Severity classification is to be done for procedures; cost-benefit analysis is to be done for projects. A procedure is defined as one or more technical acts which may cause that animal pain, suffering distress or lasting harm, and takes into account any intervention or manipulation of an animal.

There was a lot of discussion on the first classification 'up to mild and including mild' or 'mild'. In view of the request for the definition of a lower threshold, the denomination of the category 'mild' was retained. Also the assignment criteria and elements to take into account led to intense discussions. Once the semantics were agreed upon, experts were then divided into several groups to define examples of each of the various severity classifications and to decide on how severity should be assigned.

The severity shall be assigned based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

For the upper threshold, it was requested that a safeguard clause be included.

Examples provided were just meant to give guidance; the reason being that if an exhaustive list was provided, some Member States might use those as binding (and not leave room for flexibility, and not accept that a refinement introduced could possibly allow a procedure to be classified in a less severe category).

The report is available at

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/report_ewg.pdf

No further input is expected. However, two issues would be further discussed: retrospective severity assignment for reuse and for statistical reporting. The meeting date is not set yet.

This means that the interpretation of Article 16 of the Directive is still open for interpretation.

Duly submitted August 12, 2009