

Severity classification

Laboratory animal legislation seminar

12. Nov 2014

Laboratory Animal Centre, University of Oulu

Sakari Laaksonen

Severity classification of animal experiments

- Severity categories: non-recovery, mild, moderate, severe
- 1) Preliminary estimate of the severity is done in the project licence application. The licence board assigns the classification for the project licence.
- 2) The actual severity must be assessed by the researcher separately for each animal, after it has been removed from the experiment.
- 3) "Severe project" → retrospective assessment of the project (also in a "moderate project", if deemed necessary by the licence board)

Severity assignment criteria

- **Everything done and caused** to the animal during the project is taken into account.
- Based on the **most severe effects likely to be experienced** by an individual animal, after applying all appropriate refinement techniques.
- The well-being of the animals must be **monitored and documented** during the project so that the assessment of actual severity can be reliably done at the end.

Factors to be considered

- Types of manipulation and handling
- Pain, suffering, distress or lasting harm, and its intensity; duration, frequency and multiplicity of techniques employed
- Cumulative suffering
- Prevention from expressing natural behaviour; restrictions in the housing, husbandry and care. NB! Single housing of social species!

Additional factors that count

- Species and genotype
- Maturity, age and sex of the animal
- Training experience of the animal
- The severity of previous procedures in animals that are reused
- The methods of relieving pain, suffering and distress, including refinement of housing, husbandry and care
- Humane end points

1) Non-recovery procedures

- **Performed entirely under general anaesthesia** from which the animal shall not recover consciousness

2) Mild procedures

- **Short-term mild** pain, suffering or distress
- No significant impairment of the well-being or general condition of the animals
- **Examples:**
 - Anesthesia
 - Administering appropriate volume of substance by non-invasive methods, the substance having at most mild and short-term adverse effects
 - Non-invasive imaging with appropriate anesthesia
 - Superficial procedures
 - Tumours with no detectable adverse clinical effects
 - Breeding of GM animals with "mild phenotype"
 - Modified diet → mild clinical abnormality
 - Short-term solitary housing, or restraint in metabolic cage < 24 h

3) Moderate procedures

- **Short-term moderate** pain, suffering or distress
- **Long-lasting mild** pain, suffering or distress
- Moderate impairment of the well-being or general condition
- **Examples:**
 - Frequent application of test substances producing moderate clinical effects
 - Surgery in general anesthesia with appropriate analgesia
 - Tumours causing moderate pain, distress or interference with normal behaviour
 - Metabolic cage 1-5 days, intermediate length solitary housing
 - Modified diet leading to moderate clinical abnormality
 - Withdrawal of food for 48 h in adult rats
 - irradiation or chemotherapy with a sublethal dose, or with an otherwise lethal dose but with reconstitution of the immune system
 - Breeding of GM animals with "moderate phenotype"

4) Severe procedures

- **Short-term severe** pain, suffering or distress
- **Long- lasting moderate** pain, suffering or distress
- Severe impairment of the well- being or general condition
- **Examples:**
 - Death as end point, or fatalities are to be expected
 - Invasive, metastatic or ulcerating tumours
 - Surgery resulting in severe consequences; e.g. production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure
 - Prolonged social isolation or metabolic caging
 - Inescapable electric shocks (e.g. for learned helplessness)
 - Forced exercise until exhaustion
 - Animal found dead → always severe

Sources

- Web pages of the National Animal Experiment Board (ELLA):
 - <http://www.laaninhallitus.fi/lh/etela/hankkeet/ellapro/home.nsf/pages/indexeng> → New legislation in 2013 → Government Decree on the Protection of Animals Used for Scientific or Educational Purposes (564/2013) → Annex 3.
 - ELLA guidelines (based on the legislation), at the moment only in Finnish in the website.
- Consensus document of the EU commission on the severity assessment framework:
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/examples.pdf