Severity classification

Laboratory animal legislation seminar
12. Nov 2014
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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):
  - 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: