# Guidance on the severity classification of scientific procedures on animals including fish

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**www.norecopa.no**

# Norway's consensus-platform for the 3Rs

- One of 14 European platforms (Swecopa, Dacopa, Fincopa…) recognised by ***ecopa***
- Represents all 4 stakeholders
  - ✓ Regulators
  - ✓ Academia
  - ✓ Industry
  - ✓ Animal welfare organisations
- International consensus meetings
  - ➢ **Farm animals: 26-28 September**
- Position statements and 3R-resources
- Annual prize for 3R research
- AGM and scientific seminar

Several articles in the new EU Directive 2010/63/EU depend upon the existence of a classification system for the severity of procedures.

***Prospectively***:

- Case-by-case discussion and analysis of the likely impact of procedures
- To prevent procedures being carried out that involve severe pain, suffering or distress that is likely to be long-lasting and that cannot be ameliorated (loophole exists)

***Retrospectively:***

- in cases of potential re-use, to check the classification of the previous procedure (only animals subjected to Mild or Moderate procedures may be re-used – loophole here too)
- mandatory for all projects where Severe procedures and/or NHPs were used)
- for statistical reporting

The classification system applies to **procedures**, not to projects

**Projects** are assessed by a *harm-benefit analysis*

**What is a procedure?**

*'A combination of one or more technical acts'*

**Lower threshold**, below which the Directive does not apply:

*The amount of pain, suffering or distress caused by the introduction of a needle into the body of an animal, or by the administration of an anaesthetic for scientific purposes (excl. euthanasia)*

**Upper threshold:** beyond which no animal should be used. Severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated

## 4 severity categories:

- *Non-recovery*

  Procedures performed entirely under general anaesthesia from which the animal shall not recover consciousness

- *Mild*

  Procedures as a result of which the animals are likely to experience short term mild pain, suffering or distress. Procedures with no significant impairment of the wellbeing or general condition of the animals

- *Moderate*

  Procedures as a result of which the animals are likely to experience short term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress. Procedures that are likely to cause moderate impairment of the wellbeing or general condition of the animals

- *Severe*

  Procedures as a result of which the animals are likely to experience severe pain, suffering or distress. Procedures that are likely to cause severe impairment of the wellbeing or general condition of the animals

## *Additional factors:*

- Type of species and genotype
- Maturity, age and sex of animal
- Prevention of expression of natural behaviour (housing, husbandry, care restrictions)
- Some behavioural and nutritional studies may cross the lower threshold without physically touching the animal
- Several ”below-threshold” procedures applied to the same animal: Mild or higher
- Type and fequency of manipulation and handling (especially relevant in fish)
- Training experience of the animal to the procedure
- The actual severity of past procedures, in cases of re-use
- Nature of pain, suffering, distress or lasting harm caused by all elements in the procedure
- Intensity, duration, frequency and multiplicity of the techniques employed
- Methods used to reduce or eliminate pain, suffering and distress (including anaesthesia, analgesia, refinement of housing, husbandry and care)
- Monitoring of animals, clinical assessment, objective indicators
- Cumulative suffering
- Control animals in an experiment
- Humane endpoints (which can reduce a category from e.g. severe to moderate)
- Death as an endpoint should be avoided, use early humane endpoints wherever possible
- The classic dilemma: number of animals v. individual experience of severity
- Professional judgement

***The examples in the guidelines assume that all procedures are carried out by competent persons according to best practice***

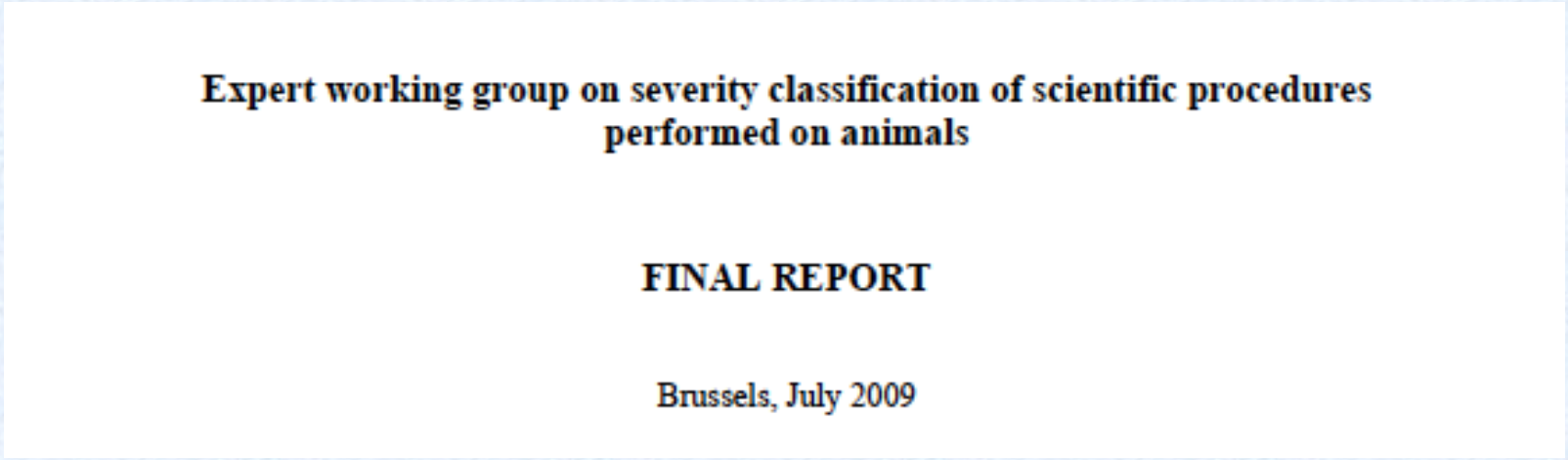
The severity category shall be assigned based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

To be based on existing classification systems (few) and ”best practice” (?)

An Expert Working Group met for 2 days in July 2009

Representatives from 18 NGOs and 22 countries

'views do not necessarily reflect those of the organisations and Member States'



**Expert working group on severity classification of scientific procedures performed on animals**

**FINAL REPORT**

Brussels, July 2009

http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

# Examples

*Below-threshold*

- Withdrawal of food for <24hr in adult rats
- Application of external telemetry devices

*Mild*

- Ear and tail biopsies
- Restraint for <24hr in a metabolic cage

*Moderate*

- Acute chronic toxicity tests with non-lethal endpoints
- Surgery associated with post-operative pain

*Severe*

- Toxicity testing with death as the endpoint
- Inescapable electric shock

- The EU EWG examples are not necessarily relevant to fish researchers, who use a range of techniques that are not used in mammals, on species that live in a different environment and that often have to be removed from their environment to be manipulated
- Norecopa commissioned a working group that spent a year gathering ideas from all stakeholders

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*Working Party Report*

**Guidance on the severity classification of scientific procedures involving fish: report of a Working Group appointed by the Norwegian Consensus-Platform for the Replacement, Reduction and Refinement of animal experiments (Norecopa)**

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**Abstract**

The severity classification of procedures using animals is an important tool to help focus the implementation of refinement and to assist in reporting the application of the 3Rs (replacement, reduction and refinement). The recently revised Directive that regulates animal research and testing within the European Union requires Member States to ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe', using assignment criteria set out by the European Commission (EC). However, these are focused upon terrestrial species, so are of limited relevance to fish users. A Working Group set up by the Norwegian Consensus-Platform for the 3Rs (Norecopa) has produced guidance on the classification of severity in scientific procedures involving fish, including examples of 'subthreshold', 'mild', 'moderate', 'severe' and 'upper threshold' procedures. The aims are to complement the EC guidelines and help to ensure that suffering in fish is effectively predicted and minimized. Norecopa has established a website (www.norecopa.no/categories) where more information on severity classification for procedures using fish, including field research, will be made available.

**Keywords:** Fish, harm–benefit assessment, humane endpoints, refinement, severity

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**Background**

An effective prediction of the effects of a research protocol on the animals concerned helps to ensure that any pain, suffering or distress they may experience will be effectively anticipated, recognized and alleviated. This is essential not only for animal welfare but also for scientific validity, because physiological and behavioural responses to suffering can significantly affect data quality. Severity classification is thus an important tool to help focus the implementation of refinement, including monitoring its progress, and to assist in reporting the application of the 3Rs (replacement, reduction and refinement) of Russell and Burch,[1] which is now an integral part of the legislation on animal research and testing in many countries. Predictions of severity are also fundamental to the harm–benefit assessments undertaken by bodies such as regulatory authorities and ethical committees when deciding whether or not a project should be licensed or funded.

There may also be a legal requirement to predict and classify severity. For example, the new Directive regulating animal use within the European Union, which must be implemented within all Member States by January 2013, requires the severity of each procedure to be classified on the basis of the 'degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure', with the aim of enhancing transparency, facilitating the project authorization process and providing tools for monitoring compliance.[2] Member States will have to ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe' on a case-by-case basis, using the assignment



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# Guidance on the severity classification of procedures involving fish

## Report from a Working Group commissioned by Norecopa

**P Hawkins (Convenor)[1], N Dennison[2], G Goodman[3], S Hetherington[4], S Llywelyn-Jones[2], K Ryder[2] and AJ Smith[6]**

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| Subthreshold* | Mild | Moderate | Severe |
|---|---|---|---|
| Feeding studies where food restriction does not cause any harm | Removal of a small part of one fin, where rapid healing and minimal dysfunction or pain are expected | Removal of scales to promote fungal growth | Saltwater/freshwater challenge where it cannot be predicted that the fish will adapt without severe effects or mortality |
| Marking using non-toxic and non-aversive dyes in the water | Gentle, brief handling of fish out of water | 'Shaking' in a net out of water to produce a stress response | Disease studies likely to cause death where the study cannot be controlled to avoid mortality |
| Manipulations of photoperiod, temperature or water gases that do not cause significant harm | Blood sampling under anaesthesia using recommended volumes and techniques | Cannulation of blood vessels followed by repeated blood sampling within recommended limits | Vaccine potency testing with persistent impairment of the animal's condition, progressive disease, or associated with long-lasting moderate suffering |

The Norecopa WG report was published in Laboratory Animals and is Open Access, thanks to sponsorship from LA Ltd.

Norecopa has set up a website with links to the severity classification guidelines and more information about the Directive and refinement for fish researchers:

**www.norecopa.no/categories**

# Project 3R-KART

Aims to

- Chart the extent to which the 3Rs are already in use in fish research in Norway
- Reveal areas where their use can be increased
- Reveal areas where research is needed to implement the 3Rs
- Increase fish welfare and the quality of fish research
- Give the Research Council guidelines on areas that should be prioritised

3R-KART consists of two phases:

- Use of an anonymous questionnaire to all facilities approved for fish research
- In-depth interviews of as many as possible of these facilities (lab and field research)

Both phases are now completed, reports are being written.

# www.norecopa.no

norecopa

Norwegian consensus platform for replacement, reduction and refinement of animal experiments

## Velkommen til Norecopa

**Latest news:**

- Alle opposisjonspartiene i Næringskomitéen ber regjeringen i forbindelse med revidert budsjett for 2012 om å øke satsingen på alternative dyreforsøk ved å styrke

**Hvem er vi?**
Om Norecopa
Historikk
Informasjonsmateriell
Ofte stilte spørsmål
Styre og sekretariat
Vedtekter
Styrets intranett

**Hva gjør vi?**
Aktivitetsplan
Årsmøter
Faglige uttalelser
Konsensusmøter
Norecopas 3R-pris
Regnskap
Styrereferater

**Bli medlem!**
Medlemmer
Medlemsfordeler
Nyhetsbrev
Tegn medlemskap!

**English section**
About Norecopa
Activities

**3Rs resources**
Categories of severity
Consensus meetings
Guidelines A-Z
Position statements
Statistical design
The Concept of the 3Rs

**Dyr i forskning**
Å planlegge dyreforsøk
Fisk
Husdyr
Laboratoriedyr
Vilt

Foto: colourbox.com

| Feedback

Søk i nettstedet

**Om Norecopa**

Norecopa arbeider for å fremme "de 3 R'ene" i forskningen som kan involvere dyr:

* **Replace**
* **Reduce**
* **Refine**

Norecopa tilstreber konsensus om de tre R'ene mellom alle de fire interessepartene rundt dyreforsøk: