

Guidance on the severity classification of procedures involving fish



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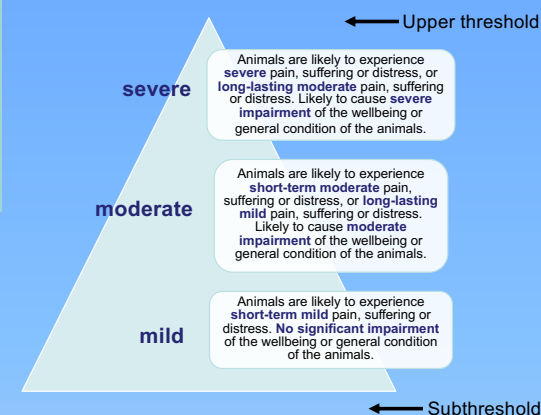
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Severity classification is an important tool in both implementing and monitoring the progress of refinement, including reporting the actual severity of procedures which is now part of the legislation on animal research and testing in some countries. 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.

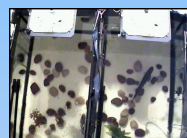
EU Directive 2010/63 requires signatories to ensure that the severity of all procedures is classified as 'non-recovery' (under terminal anaesthesia), 'mild', 'moderate' or 'severe', using assignment criteria set out by the European Commission (EC) – see diagram. 'Subthreshold' procedures are those that are expected to inflict less pain, suffering or distress than that caused by the introduction of a needle.

An EC Working Group produced a report in 2009 giving examples of procedures within these categories, but these are most relevant to research using terrestrial species.

A working group set up by the Norwegian Consensus-Platform for the 3Rs (Norecopa) has published a complementary document that gives guidance on severity classification in fish research, including examples of 'subthreshold', 'mild', 'moderate', 'severe' and 'upper threshold' procedures. This document will make it easier for fish researchers to implement the requirements of the Directive.



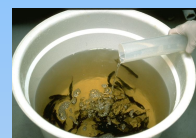
How would you categorise these procedures?



Behavioural studies



Handling out of water



Anaesthesia



Injection under anaesthesia

Examples from each category in Norecopa's guidelines (simplified):

Subthreshold

- Behavioural studies
- Feeding studies where food restriction does not cause any harm
- Marking using non-toxic and non-aversive dyes in the water
- Manipulations of photoperiod, temperature or water gases that do not cause significant harm

Mild

- Disease research where humane endpoints are applied at the first clinical sign of disease or earlier
- Gentle, brief handling of fish out of water
- Blood sampling under anaesthesia using recommended volumes and techniques
- Removal of a small part of one fin, where rapid healing and minimal dysfunction or pain are expected
- Toxicological studies where animals are humanely killed at or before the onset of clinical signs

Moderate

- Cannulation of blood vessels followed by successive blood sampling within recommended limits
- Intraperitoneal injection of substances known to cause adhesions
- Intramuscular or intraperitoneal implantation of telemetry devices by surgical procedures (under general anaesthesia)
- External attachment of telemetry devices with a risk of interference with normal activity and behaviour
- 'Shaking' in a net out of water to produce a stress response
- Removal of scales to promote fungal growth

Severe

- Saltwater/freshwater challenge for scientific purposes where it cannot be predicted that the fish will adapt without severe effects or mortality
- Disease studies likely to cause death where the study cannot be controlled to avoid mortality
- Vaccine potency testing with persistent impairment of the animal's condition, progressive disease leading to the animal's death, or associated with long-lasting moderate pain, distress or suffering
- Surgical interventions under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress

Upper threshold

- Pathophysiological studies where animals will experience substantial pain, suffering or distress which is long lasting
- Description of survival curves or similar tests where death is an endpoint and where death is preceded by prolonged and substantial pain, suffering or distress

Norecopa has set up a website with links to these guidelines and more information on severity classification:

<https://norecopa.no/categories>

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