

Guidance on preparing documentation for the retrospective assessment

This guidance should assist the submission of the necessary documentation for a retrospective assessment according to § 30 TVG 2012. The suggestions here may not be applicable to all cases, depending on the project. However, sometimes additional more specific questions may arise.

Purpose of the retrospective assessment

The retrospective assessment should make it possible to use experiences from the project

- to find elements that may contribute to further implementation of the 3Rs (reducing the number of animals used, refining the use of animals, replacing the use of animals in procedures),
- to review critically the use of animals in procedures, and
- to inform the public in a transparent and objective manner (through publication of the updated non-technical summary).

Data for Reference

Title of the project:

The permit for the project was issued under (GZ.):

Amendments to the project permit, if any:

Project leader:

Documentation for the retrospective assessment

The documentation for the retrospective assessment should at least enable the evaluation of the following:

I. Achieving the objectives of the project

- Explain to what extent the objectives set out in the project proposal were achieved (including a short presentation of the results).
- Reasons why objectives were not achieved.
- Other, additional results?

- Which benefits have resulted from the project up to now, is any further benefit to be expected?
- Are the results to be published (e.g. in peer reviewed journals, presented at conferences, used in education)?

II. Harm to the animals

- Information about the harm to the animals. How many animals were used, which species, data about the actual severity experienced by the animals.
- Comparison with the (expected) information stated in the project proposal (animals foreseen, expected severity). Explain any deviations.

III. „3R“

- Are the models used still the most suitable models?
- Was the number of animals adequate for **statistical analysis**?
- Could the **design of the project** be further optimized in the future to reduce the number of animals or the number of severely harmed animals (e.g. by modular design of the project – using „milestones“, reduction of group sizes through interim statistical analysis)?
- Could the use of animals be further reduced by other approaches?
- Was the foreseen **anesthesia/analgesia** adequate? Could the methods for anesthesia/analgesia be further improved to reduce pain and suffering for the animals? Which observations were made?
- Which **humane endpoints** were reached? Which observations were made?
- Could the humane endpoints be improved to reduce the harm to the animals?
- Were there improvements in the monitoring of the animals during procedures?
- Were the protocols for scoring/evaluation adequate?
- Could **killing methods** be improved? Any observations?
- Developments which could make the use of animals fully or partially unnecessary (e.g. new in-vitro- or in-silico-methods)?

- Measures taken during the project to reduce the harm to the animals
- Describe possible measures that may contribute to further implementation of the 3Rs.
- How could harm to **animals in procedures** be reduced in **the future**?
- How could strategies be further improved (e.g. route of administration/sampling; surgery)?
- How could monitoring be improved to ensure that sick or injured animals are identified and appropriate measures are taken?
- Describe how conditions for **housing, accomodation and care** could be improved. Further stay of animals after the end of the procedures (e.g. rehoming, suitable husbandry system), if applicable.
- Were there any **recommendations from the animals welfare body** to the project?

IV. Update of the non-technical project summary

(based on the information given in the non-technical project summary in the project approval – easily comprehensible, intended for the general public)

- Explain to what extent the objectives set out in the project proposal were achieved.
- Information about the harm to the animals, including number, species and the actual severity experienced by the animals.
- Describe all measures that contributed or may contribute to further implementation of the 3Rs.

The result of the retrospective assessment will be communicated to the user and to the project leader. With the completion of the retrospective assessment the obligation according to § 31 Abs. 3 TVG 2012 to keep the documentation ends.

Any obligation according to § 31 Abs. 3 TVG 2012 to keep the documentation longer than minimal period of the 3 years ends with the completion of the retrospective assessment.

Further information can be found in the working document on project evaluation and retrospective assessment of the European Commission:

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