



LINZ 2013 18th European Congress on Alternatives to Animal Testing
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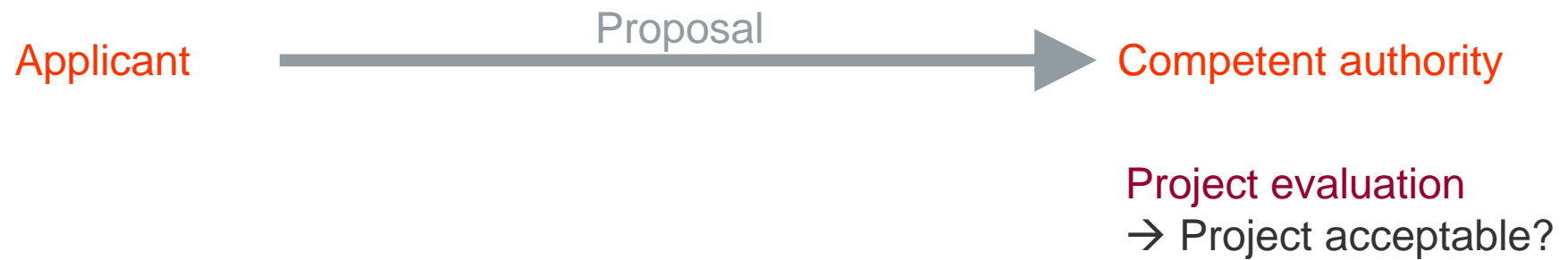
A catalogue of criteria to objectify the harm-benefit analysis according to Austrian legislation

Project: Developing a methodology to evaluate animal experiments
funded by the Austrian Federal Ministry for Science and Research

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1. Proposal by the researcher



2. Project evaluation by the authority

Directive 2010/63/EU*) → Austrian Animal Experimentation Act (TVG 2012)

Project evaluation shall verify that the project meets the following criteria**):

- the **project is justified** from a scientific or educational point of view **or required by law**
- the **purposes of the project justify** the use of animals
- procedures to be carried out as **painlessly***)** and in the **most environmentally sensitive manner possible**.

*) European Parliament (2010): Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. In: *Official Journal of the European Union* October 20, 2010 L 276/33-79. Article 38 (Project evaluation)

**) Tierversuchsgesetz 2012 - TVG 2012. (Austrian) Animal Experimentation Act 2012, Federal Law on Experiments on Live Animals (*BGBI.* I No. 114/2012 of 28 Dec. 2012); § 29 (1) ("Projektbeurteilung")

***) Directive: "in the most humane [...] manner possible"

2. Project evaluation by the authority

Project evaluation shall consist in particular of the following*):

- evaluation of the **objectives** of the project, the **predicted scientific benefits** or **educational value**;
- assessment of the **compliance** with the **requirements** of the **3Rs**
- assessment and assignment of the **classification of the severity**
- **harm-benefit analysis**

*) § 29 (2) TVG 2012 ("Projektbeurteilung")

3. Harm-benefit analysis

“a **harm-benefit analysis** of the project, to assess whether the **harm to the animals** in terms of suffering, pain and fear*) is **justified by the expected outcome taking into account ethical considerations**, and **may ultimately benefit** human beings, animals or the environment,



in which the completed catalogue of criteria [...] has to be considered,” **)

The Minister for Science and Research publishes***)

- **until 31 Dezember 2015**
- **a catalogue based on scientific criteria**
- **in order to objectify the harm-benefit analysis**

*) Directive: “distress”

***) § 29 (2) No. 4 TVG 2012

****) § 31 (4) TVG 2012

4. Requirements for an appropriate catalogue

- **structuring the discussion**
- **objective and transparent decision making**
- **fair evaluation**
- **intersubjective comparing of results** (cf. review Varga *et al.**);
→ aspect of justice; coherent standard of protection
- **integrate ethical criteria**
into the evaluation procedure
which will be typically carried out by non-ethicists

*) Varga, O., Sandoe, P. and Olsson, I.A.S. (2012): Assessing the animal ethics review process. In: Potthast, T. and Meisch, S. (Eds.): *Climate change and sustainable development. Ethical perspectives on land use and food production*. Wageningen Acad. Publishers, 462 – 467.

4. Requirements for an appropriate catalogue

- a. **assistance for the researcher** to provide the relevant information
 - b. **assistance for the authority** who conducts the project evaluation but not intended to replace a well informed responsible decision
-
- **should include *all* relevant criteria**

5. Relevant criteria

Annex VI of the Directive 2012/63/EU:
Aspects that a proposal has to comprise for approval
→ § 21 Austrian Animal Experiment Regulation (TVV 2012*)

*) Tierversuchs-Verordnung 2012 – TVV 2012 (BGBl. II No. 522/2012 of 28 Dec. 2012)


Directive 2012/63/EU
RICHTLINIE 2012/63/EU DES EUROPÄISCHEN PARLAMENTS UND DES RATES vom 22. September 2012 zum Schutz der für wissenschaftliche Zwecke verwendeten Tiere

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ANNEX VI
LIST OF ELEMENTS REFERRED TO IN ARTICLE 37(1)(c)

1. Relevance and justification of the following: (a) use of animals including their origin, estimated numbers, species and life stages; (b) procedures.	VI 1a) Use Origin Numbers Species Life Stages
2. Application of methods to replace, reduce and refine the use of animals in procedures.	VI 1b) Method
3. The planned use of anaesthesia, analgesia and other pain relieving methods.	VI 2. 3R's
4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.	VI 3. Anaesth. Analges. Pain Relieving
5. Use of humane end-points.	VI 4. Minimising of Pain (Lifespan)
	VI 5. Humane endpoints

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6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.	VI 6. Experimental or observational strategy
7. Reuse of animals and the accumulative effect thereof on the animals.	VI 6. Biostatistics
8. The proposed severity classification of procedures.	VI 7. Re-use (accumulative effect!)
9. Avoidance of unjustified duplication of procedures where appropriate.	VI 8. Severity Classification
10. Housing, husbandry and care conditions for the animals.	VI 9. Duplication of Experiments
11. Methods of killing.	VI 10. Housing, Husbandry, Care
12. Competence of persons involved in the project.	VI 11. Killing
	VI 12. Qualification

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6. Categories

A1) General project data

A2) Assignment to one of the legal purposes

Information about special aspects:

Duplication of experiments

Experiments using special species

Reuse of animals

...

B) Alternatives? / Indispensability

C) Importance of the project (incl. benefit)

D) Quality of the experiment
Scientific quality and efficiency
Quality of the personnel

E) Burdens of the animals

F) Breeding, husbandry and care

G) Harm-benefit analysis

H) Retrospective assessment

7. Structure of the questions

Symposium at the Messerli Research Institute, March 2013:
“Taking Ethical Considerations into Account? Methods to Carry Out the Harm-Benefit Analysis According to the EU Directive 2010/63/EU.”



Photos: <http://www.vetmeduni.ac.at/en/messerli/infoservice/messerli-news/symposium-on-the-ethical-evaluation-of-animal-experiments/photos/>

7. Structure of the questions

- 1) Checklist structure
- 2) Scoring methodology
- 3) Comparative approach



7. Structure of the questions

1) Checklist structure (*checking facts*)

- “Yes” / “No” respectively “correct” / “not applicable”

e.g.:

Does the leader of a project including surgery has an academic qualification corresponding to § 27(1) No.1 TVG 2012*)? Yes

No

If not, does she/he has a corresponding education, which one: _ _ _ _ _

Yes

No

Does the leader has sufficient specialized knowledge? Yes

Which one: FELASA-Course category C _ _

No



*) § 27 (1) (“Projektleiterinnen oder Projektleiter”) No. 1
TVG 2012 in conjunction with § 19 (2) No. 2 TVG 2012

7. Structure of the questions

2) Scoring methodology (evaluation by *weighting* of issues)

- Questions will be answered according to each category
- The applicant is asked to describe an issue
- Additionally he has to answer specific questions by grading (e.g. 1–5) or awarding points (ready answers are offered)
- For the project evaluation, the authority/committee makes its own assessment and checks if the applicant's estimation is plausible

7. Structure of the questions

2) Scoring methodology (evaluation by *weighting* of issues)

- After describing the issue the researcher has to answer additional questions, e.g.:

Realistic potential of the experiment to achieve the objective	Estimation Researcher	Estimation Authority
	<ul style="list-style-type: none"> <input type="radio"/> 1. Excellent <input checked="" type="radio"/> 2. Very good <input type="radio"/> 3. Good <input type="radio"/> 4. Average <input type="radio"/> 5. Inadequate 	<ul style="list-style-type: none"> <input type="radio"/> 1. Excellent <input type="radio"/> 2. Very good <input checked="" type="radio"/> 3. Good <input type="radio"/> 4. Average <input type="radio"/> 5. Inadequate

- The proposed evaluation by grades is based on the project evaluation for funding as used by the FWF*) in Austria

*) Fonds zur Förderung der wissenschaftlichen Forschung (Austrian Science Fund) FWF (2012): Bewertungshandbuch für das „Translational-Research-Programm“, Appendix I: Fragen an FachgutachterInnen eines TRP-Projekts, Section 1. Note: The criteria aim also to projects in the field of basic research, see Section 1 No. 1.

7. Structure of the questions

3) Comparative approach

- Extremes for the adjustment of the catalogue
- Which appraisals are a “no go”, cf. Zurich “Negative List”*)



*) Liste nicht mehr zulässiger Tierversuche an den Zürcher Hochschulen (List of animal tests which are no longer allowed at institutes of higher learning in Zurich). In: *ALTEX* 14, 2/97, 61-62.
<http://www.altex.ch/resources/Negativliste.pdf>

8. Overall judgement

Harm-benefit analysis

- Presumably, the results of each category will be determined
- the results of each category go into the overall judgement (harm-benefit analysis)



9. The project

Outline

- 2013 – June 2014: development of the Austrian Catalogue of Criteria
- June 2014 – June 2015: evaluation of the catalogue
- Dec. 2015: final report



Thank you for your attention!

