Taking Ethical Considerations into Account? Methods to Carry Out the Harm-Benefit Analysis According to Directive 2010/63/EU

European Directive 2010/63/EU had to be transposed into national law in all EU Member States. Article 38 (2) emphasizes that a harm-benefit analysis has to be carried out for every experiment involving live animals in order to assess whether the harms caused to the animals within a project are justified by its expected benefits. The passage on harm-benefit analysis also addresses ethical considerations that have to be taken into account. Therefore, it is crucial to define what the term “taking into account ethical considerations” means to resolve the question how the harm-benefit analysis can be carried out. This is especially true since the term provides a legally binding basis for the approval or disapproval of projects. In other words: Everybody who aims at a project authorization in Europe has to answer the question regarding its ethical justification on legal grounds.

In March 2013, the Messerli Research Institute at the University of Veterinary Medicine, Vienna, hosted an international symposium on harm-benefit analysis against the background of the European Directive. The aim of this symposium was to bring together experts to exchange views about methods of harm-benefit analysis and build up comprehensive state-of-the-art knowledge on it. More than 20 speakers from eight EU Member States and the USA followed our invitation and contributed to the issue with their experience, ideas and arguments. We are very grateful that many of them were willing to put down their talks in papers in form of extended abstracts. Thanks to these efforts, even a wider community can benefit from the outcome of the symposium.

In order to mention some of the main results, we would like to address the following points in brief: First, different concepts of harm-benefit analysis, such as checklists, scoring systems or comparative methodologies were introduced and discussed in the course of the symposium. Their relative strengths and weaknesses lead to the idea that combining the strengths of methodologies can fuel new developments in this field to lead to a more thorough reflection on animal experiments. Second, the importance of carrying out the evaluation procedure according to appropriate and transparent criteria, which should be weighted on the harm- and benefit-side, was highlighted. When the question arose who was going to use such methodologies during the approval procedure of a project, most of the experts highlighted the importance of independent, well-balanced committees. Therefore, third, a strong point was made that committees on local and national levels should be involved in the design and execution of the evaluation procedure. Further, taking the public opinion into account and integrating lay people and representatives of animal protection groups in the committees could contribute to transparency and trustworthiness. A fourth point of major relevance addressed the changing status of animals in our societies. Whereas the aim of a harm-benefit analysis is to limit the use of animals for scientific purposes to projects in which the harms caused to the animals are justified by its expected benefits, it should be considered that the use of animals as such can not be taken for granted without further questioning. Also pragmatic aspects were addressed, such as the risk of over-bureaucratization: Any methodology for the harm-benefit analysis should be user-friendly.

These and other aspects are relevant for all EU Member States that have to live up to the Directive and corresponding national laws. In Austria, we face the challenging situation that the new Austrian Animal Experimentation Act, which transposed the Directive 2010/63/EU into national law in 2012, requires the development and publication of a catalogue of criteria to objectify the harm-benefit analysis of projects including animal tests. This catalogue has to be designed to weigh “harms” inflicted on laboratory animals such as pain, suffering, fear/distress and lasting harm against “benefits” for humans, animals and/or the environment. The catalogue has to be published by the Federal Ministry of Science, Research and Economy by the end of 2015. All applicants in Austria have to fill in this Austrian Catalogue of Criteria and submit it as a part of their application to the respective competent authority six months after its publication at the latest.

The Federal Ministry of Science, Research and Economy engaged the Messerli Research Institute to develop the Austrian Catalogue of Criteria. The challenge for the project team is to balance advantages and disadvantages of the various methods and to develop an adequate model to weigh the “harm” of animals against the “benefit” for humans, animals and/or the environment and all this against the background of Austrian legislation.

We hope that this publication will promote the debate on the harm-benefit analysis in animal research and provide a basis for further developments.

Herwig Grimm, Norbert Alzmann and Vera Marashi

Acknowledgement
The project is funded by the Austrian Federal Ministry of Science, Research and Economy (reference number: BMWF-10.240/0018-II/3/2012).