Balancing Competing Values in a Legal Setting: Evaluating Harm and Benefit of Proposed Animal Experiments

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Summary
This paper is intended to provide a basic introduction to the problems connected with the balancing of legally protected interests in general and to the legal framework constituting the basis for the harm-benefit analysis in the context of the new European laboratory animal legislation in particular.

Keywords: Directive 2010/63/EU, Austria, harm-benefit analysis, legally protected interests, Kriterienkatalog

1 Directive 2010/63/EU

After a long controversy on the question if animal experiments should be ethically assessed in the course of the administrative project evaluation, Art. 38/2 d) of the Directive 2010/63/EU on the protection of animals used for scientific purposes rules that the project evaluation has to include “a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment; (…)”. The obligation to assess the ethical acceptability of applications is explained in greater detail by recital no. 39, stating that it is regarded as “essential, both on moral and scientific grounds, to ensure that each use of an animal is carefully evaluated as to the scientific or educational validity, usefulness and relevance of the expected result of that use. The likely harm to the animal should be balanced against the expected benefits of the project.”

Thus, a harm-benefit analysis in the sense of Directive 2010/63/EU has

- to balance adverse effects likely to be inflicted on the animals against beneficial effects expected to result from their experimental use;
- to be carried out prospectively by the competent authority in an impartial way, i.e., independently of persons involved in the study.

2 Austrian Act on Animal Experiments 2012 (Tierversuchsgesetz 2012)

The member states were obliged to transpose Directive 2010/63/EU into national legislation by January 1, 2013. In Austria, the previously mentioned requirement is enacted in § 29/2/4 of the Austrian Act on Animal Experiments 2012 (Tierversuchsgesetz 2012 – TVG 2012). As a specific requirement § 29/2/4, TVG 2012 rules that each application – from the July 1, 2016 onwards – has to include a “completed form” on the criteria necessary for carrying out a harm-benefit analysis. This form, the so-called Kriterienkatalog which is being developed by the Messerli Research Institute, has to be published by the Federal Minister of Science, Research and Economy by the end of 2015.

Although the obligation to carry out a harm-benefit analysis is something entirely new for most of the EU member states, this is not true for Austria. According to § 3/2/1 of the former Austrian Act on Animal Experiments (TVG 1989), a “justifying interest” was necessary for a project to be authorized. According to the

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2 According to Art. 38/3 of the Directive it is, however, not necessary to include ethicists into the authorisation process.
3 Bundesgesetz über Versuche an lebenden Tieren (Tierversuchsgesetz 2012 – TVG 2012), BGBl. I Nr. 114/2012 v. 28.12.2012, Art. 1. In German, the clause reads as follows: “(…) 4. eine Schaden-Nutzen-Analyse des Projekts, in deren Rahmen bewertet wird, ob die Schäden für die Tiere in Form von Leiden, Schmerzen und Angst unter Berücksichtigung ethischer Erwägungen durch das erwartete Ergebnis gerechtfertigt sind und letztlich Menschen, Tieren oder der Umwelt zugute kommen können, wobei der ausgetüftelte Kriterienkatalog gemäß § 28 Abs. 2 Z 8 zu berücksichtigen ist, (…)”
4 Cf. also §§ 26/2/8, 31/4 and 42/7 TVG 2012.
3 General considerations on balancing competing interests in a legal context

In the following section, some of the most challenging aspects of legal decisions brought about by balancing interests are discussed; they should be explored in greater detail in the course of the development of the Kriterienkatalog.

3.1 Deciding versus balancing

Basically, there is nothing unusual about weighing and balancing competing interests in the process of legal decision-making. Originally, however, balancing of interests as a legal instrument was developed in ancient Roman civil law, aiming to evaluate the pecuniary value of conflicting interests of private individuals. Balancing interests is closely linked to the principle of proportionality, determining that all relevant interests have to be considered appropriately. It was only in the 19th century when proportionality was acknowledged as a principle of public law. In the 1950s, German jurisdiction developed a scheme for assessing questions of proportionality, differentiating three stages of evaluation: suitability, necessity and proportionality (in the narrower sense); similar schemes are applied by the Court of Justice of the European Union and by Austrian courts (Koch, 2003).

In today’s jurisdiction, it is rather common to balance incommensurable interests, e.g., the interest in environmental protection against the interest in creating jobs, the interest in recreation and health versus the interest in stimulating the economy or in the expansion of traffic routes. It is important to notice that the principle of proportionality always means “more or less” or “as well as” instead of a binary decision of “yes or no”. Therefore, it should be quite obvious that the ideal of proportionality may contribute to the ambiguity of juridical decisions. Thus, evidently, there is a tension between proportionality on the one hand and the principles of legality and constitutionality on the other hand (Leisner, 1997).

With regard to legal provisions on animal welfare (including animal experiments), the necessity to weigh and balance interests directly results from the mainly consequentialist structure of these legal matters: Only very few welfare provisions are designed as deontological rules, laying down absolute bans and allowing for a definite decision (e.g., the general prohibition of using Great Apes and Gibbons for experimental purposes, § 4/5 a) TVG 2012).

3.2 Procedural aspects of “balancing decisions”

Before carrying out a harm-benefit analysis, it is important to distinguish the following steps: it is necessary a) to identify and define a proper understanding of the relevant interests, b) to assess their value or significance in a methodically correct, coherent and convincing way and c) eventually to balance the values and make a decision (Binder, 2008). Thus, it is clear that balancing interests is to be regarded as a process, whereas proportionality is (or should be) the result of this process. The most crucial challenge of the balancing process has to be tackled in stage b) when the definite significance of the conflicting values has to be determined.

3.3 Types of interests

With regard to the types of values or interests which have to be considered in the balancing process, we can distinguish between weighing of a) private versus private, b) private versus public, and c) public versus public interests. Within the context of animal experiments, it is not the scientist’s individual interest in carrying out an experimental procedure which has to be balanced against animal protection, but the public interest in scientific progress which has to be weighed against the adverse effects likely to be inflicted on the animals and against the acknowledged public interest in animal welfare (cf. 3.4).

3.4 Converting interests

Assessing the significance of inherently different values, it is crucial to identify a common denominator if it proves impossible to apply a monetary conversion key. Although legislation increasingly relies on or requires balancing of public interests, a legislative clue on how the evaluation and balancing should be carried out is usually lacking; there is, for example, no tool to specify how much the freedom of assembly and demonstration should count with regard to the interest in fluid traffic and transportation. Depending on the specific issue, various criteria are applied, for example the question how seriously a constitutional right (e.g., property right) is being infringed by an administrative act (e.g., a restrictive covenant) or the question of how many people are affected by a specific (e.g., structural) measure. As to the harm-benefit analysis of animal experiments, the problem of convertibility seems to be still more accentuated because non-human interests have to be dealt with in a legal context designed to meet more or less exclusively human demands. With regard to the process of assessing the animal interest⁶ in

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⁵ The original wording reads as follows: “Für die Zulässigkeit von Tierversuchen ist schließlich immer das Ergebnis einer Güterabwägung entscheidend, die zwischen dem Schutz für die Tiere einerseits und dem Fortschritt der dem Schutz des Lebens und der Gesundheit von Mensch und Tier dienenden Wissenschaften andererseits vorzunehmen ist.” (Explanatory report to the Act on Animal Experiments enacted in 1989); cf. also Binder (2009a), 60ff.

⁶ Cf. Binder (2009b), 245ff. on different positions towards animal interests.
well-being, it should be noted, however, that this concern can be converted into a public (and therefore strong anthropocentric) interest in animal welfare, as acknowledged by legislation, as well as by jurisdiction. Moreover, it is important to mention that basic and applied research but also animal welfare were acknowledged as state objectives in Austria in 2013.

3.5 The importance of reasoning
With regard to the principles of legality and constitutionality, it should be possible to reconstruct all circumstances and sub-decisions of the balancing process. Decisions made by balancing are, however, often characterized by unsatisfactory or even lacking reasoning, using mostly more or less empty phrases and formulae or even only copying the wording used by the legislator (Leisner, 1997).

4 Balancing harm inflicted on animals against benefits for humans, animals or the environment

4.1 “Harm” – adverse effects inflicted on laboratory animals
With regard to the evaluation of the aspects of “harm”, the Directive sets up a tool to assess the adverse effects (pain, suffering, distress, lasting harm) inflicted on the animals by establishing a classification scheme in Annex VIII, which was transposed into Austrian Law by § 3 TVG 2012. According to recital no. 22, the severity classification is to “enhance transparency, facilitate the project authorisation, and provide tools for monitoring compliance.” In line with Art. 15/1 of Directive 2010/63/EU, the expected severity of a procedure has to be “classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case-by-case basis using the assignment criteria set out in Annex VIII.”

Thus, laboratory animal legislation provides a rather detailed scheme to assess adverse effects (i.e., pain, suffering, distress or lasting harm) inflicted on animals; combined with the quite extensive expert knowledge on assessing the condition of animals and on the effects of 3R strategies, it should basically be possible to objectively assess adverse effects, even though there are of course unsolved problems (e.g., with regard to the expected harm of future generations of transgenic animals), as well as an overall potential to render future assessment more accurate.

4.2 “Benefit” – advantageous effects on humans, animals or the environment
On the other hand, neither the Directive nor Austrian laboratory animal legislation provides any clue how to assess the potential benefit of a procedure. It is clear, however, that any legitimate animal experiment has to comply with the purposes defined by § 5 TVG 2012, which might suggest that any experiment pursuing one of these purposes has to be attributed the “benefit of the doubt” for being ethically justified.

This assumption, of course, also applies to projects of basic research which are doubtlessly legitimate in line with the relevant provisions, although they can, by definition, not be assessed prospectively with regard to any concrete benefit. So-called “regulatory” animal experiments, on the other hand, are carried out to provide data on product safety prescribed by law; as long as there is no alternative method available to generate these data, there is no way to reject the ethical acceptability of such experiments without contradicting a previous legislative decision. The only way to question the ethical acceptability of such experiments would be de lege ferenda, i.e., on the basis of a future revision of the relevant legal provisions.

Finally, with regard to assessing the significance of beneficial effects possibly resulting from animal experiments, it should be considered that human interests in generating knowledge from animal experiments are usually far stronger than human interests involved in many other kinds of animal use (Binder, 2014).

5 Balancing interests in the context of general animal welfare legislation

Regarding the general animal welfare law as codified in the Austrian Animal Welfare Act (AWA), it is important to notice that assessing the question of which kinds of animal use may be regarded as legitimate mostly depends on the interpretation of indeterminate legal concepts, such as “unjustified” infliction of pain, suffering, severe anxiety or harm (§ 5/1 AWA) or the “justifying reason” for killing an animal (§ 6/1 AWA). Without being explicitly mentioned in the AWA, these decisions are also made by balancing the interest in animal protection against the interest in using animals for various purposes. It was Robert Garner who recently suggested developing binding criteria to interpret these inherently vague legal terms in order to delimit and – in the long term – eventually even stop animal use (Francione and Garner, 2010).

6 Summary and conclusion

Balancing incommensurable interests is a serious challenge, but by no means an uncommon phenomenon in judicial proceedings. It is even a quite common instrument in general animal welfare legislation. Legal history shows that balancing values

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7 Cf. Explanatory report to the AWA (446 -Big NR 22. GP 2); e.g., VfGH v. 17. 12. 1998, B 3028/97; v. 12. 7. 2005, G 73/05; v. 1.12.2011, G 74/11-10, V 63/11-10.
8 Bundesverfassungsgesetz über die Nachhaltigkeit, den Tierschutz, den umfassenden Umweltschutz, die Sicherstellung der Wasser- und Lebensmittelsversorgung und die Forschung, BGBl. I Nr. 111/2013 v. 11.7.2013.
was originally a typical instrument of civil law, aiming to coordinate interests among individuals. Weighing and balancing public interests only started in the 19\textsuperscript{th} century, intending to protect the individual against an unproportional infringement of constitutionally granted rights. Since the 1950s, German jurisdiction has developed a three-stage assessment scheme which was partly adopted by Austrian courts and further developed by the Court of Justice of the European Union.

With regard to the harm-benefit analysis of projected animal experiments, it should be noted that the competent authorities have been obliged to balance harm against benefit since January 1, 2013. The \textit{Kriterienkatalog} which has to be published by the Minister of Science and Research by December 31, 2015

– is intended to simplify the balancing process and to objectify its results;
– is not intended to be normative in the strict sense of the word and should therefore be regarded as a guideline to carry out the harm-benefit analysis;
– is to provide the basis of decision making for the competent authorities, while the actual task of balancing and deciding rests with the authorities.

With regard to balancing values in the given context, it should be noted that there are public interests involved not only on the side of the benefits, but also on the side of harm. The harm-benefit analysis is a highly complex process which should be standardized for different reasons (Binder, 2009a); on the other hand, it might be doubted if any mathematical formula or mechanical method can be used successfully to come to proportional, transparent and reasonable decisions in the context of legal proceedings.

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