



Evaluation Process for Animal Experiment Applications in Switzerland

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Summary

As Switzerland is not a member of the EU, the respective EU Directive is not binding on the Swiss authorities or legislature. The harm-benefit analysis, however, has been an integral part of Swiss animal experimentation legislation for years. Hence, a certain practice has been established in Switzerland.

Keywords: Harm-benefit analysis, severity grade catalogue, Switzerland, dignity of animals, ethical questions

1 Severity grades and permitting procedure

A severity grade catalogue¹, launched in 1995, divides every application for an animal experimentation project into four categories from 0 to 3. Severity degrees 1 to 3 are those declared burdensome to the animal, with degree 3 including extremely severe tests or moderately severe tests over a long period. For all experiments of degrees 1 to 3, examination by a cantonal committee for animal experimentation is mandatory. This committee advises the cantonal veterinary authority as the licensing body.

Severity degree 0, meaning that there is no pain, suffering, damage or anxiety inflicted on the animal, is authorized by the cantonal veterinary authority without mandatory examination by the cantonal committee for animal experimentation. It is worth mentioning that severity degree 0 includes tests in which the animal is killed painlessly to extract organs, tissue, cells, etc. due to the legislative opinion that death does not constitute any kind of damage contemplated in the grade catalogue (this opinion is challenged in scientific literature) (Goetschel and Bolliger, 2003, p.215; Gerritsen and Rüttimann, 2012, p.263).

When applying for an animal experiment project license, the researcher has to determine the expected degree for all animal groups undergoing burdensome manipulations, detailing in Form A (Application to Perform Animal Experiments)² which animals are going to suffer, in which way, and how much. Af-

ter completing the approved animal experiment or at the end of each year, the researcher has to fill out Form C (Report on Animal Experiment)³, re-evaluating the degree of suffering of every animal used, based on the facts and data resulting from the project. Corresponding criteria are defined in a further catalogue which focuses on monitoring behavior parameters and signs of pain in various animal species.⁴

2 Harm-benefit analysis in theory and practice

In theory, legislation is clear.⁵ Literature, both scientific and by animal welfare groups, agrees: the infliction of pain, suffering, damage or anxiety to an animal must not be licensed if there is no evidence of a benefit overbalancing⁶ the animal's suffering. The more severe the harm, the greater the need for justification (Akademien der Wissenschaften Schweiz, 2005, p. 3; EKAH/EKTV, 2001, p. 7f.; Zenger, 1989, p. 118f.; Kley and Sigrist, 2011, p. 37); consequently, the benefit has to be more important, more realistic, and more promptly realizable. The frequently cited *Ethical Principles and Guidelines for Scientific Animal Testing* by the Swiss Academies of Arts and Sciences state that some experimental designs presumably inflict pain or suffering classified as so severe that the harm to the animal cannot be outweighed by any human benefit. If the design cannot be changed in order to alleviate suffering, there is a moral obligation to ab-

¹ Bundesamt für Lebensmittelsicherheit und Veterinärwesen BLV, Einteilung von Tierversuchen nach Schweregraden vor Versuchsbeginn (Belastungskategorien), Allgemeine Leitsätze und Beispiele zur analogen Klassierung weiterer Versuche, Information Tierschutz 1.04, available at <http://www.blv.admin.ch>.

² Form A: Application to Perform Animal Experiments (V1.4), and respective explanatory notes. All forms are available on <http://www.blv.admin.ch>.

³ Form C: Report on Animal Experiment (V1.3), and respective explanatory notes, see footnote 2.

⁴ Bundesamt für Lebensmittelsicherheit und Veterinärwesen BLV, Retrospektive Einteilung von Tierversuchen nach Schweregraden (Belastungskategorien), Information Tierschutz 1.05, available on <http://www.blv.admin.ch>.

⁵ Art. 19 Abs. 4 TSchG.

⁶ Art. 3 lit. a TSchG: overbalancing interests are required to justify harm inflicted upon animals.



stain from the experiment and the desired benefit (Akademien der Wissenschaften Schweiz, 2005, p. 3, § 3.5).

In practice – I am speaking as a member of the committee for animal experimentation of the canton of Zurich⁷ – the aforementioned is not what is actually happening. The harm-benefit analysis is generally reduced to a mere formal requirement that can easily be fulfilled by the researcher by explaining that the described project has the potential to contribute to the development of new therapies. The committee for animal experiments only raises objections to an inadequate or insufficient evaluation of interests if there are formal deficiencies, e.g., if the researcher has failed to weigh up the damage and suffering of the animal against the alleged benefit. As soon as the formal requirements are met, the committee no longer deals with this aspect.

A real harm-benefit analysis or an examination of all interests concerned is usually not carried out by the committee or by the licensing authority. It is implied that health benefits outweigh and even overbalance the harm done to animals even if their suffering is considered to be within severity degree 3. In fact, the committees perceive themselves as 3R boards, trying to disburden the animals in use without questioning their disposability regarding the actual project. Only in rare cases of poorly described experimental designs, project applications are challenged with respect to the harm-benefit analysis and rejected, giving the researcher ample opportunity to revise his application.

With respect to the applicants, the Swiss Academy of Medical Sciences and the Swiss Academy of Sciences established an online self-evaluating tool available to researchers performing animal experiments.⁸ The ethical assessment guide for conflicting issues in animal experimentation enables researchers to look into ethical questions in terms of the harm-benefit analysis. The tool is designed as a points system. The researcher is asked to answer 29 questions about the expected benefit, including human health and quality of life, health and welfare of animals, as well as 3R contributions. On the cost/harm side, questions refer to grades of severity, species, number of animals used, expected further experiments involving animals, and 3R possibilities. A third category assesses the researcher's sense of responsibility.

Unfortunately, this voluntary tool seems to be used only in rare cases. Presumably, the scientists just do not have it in their minds as it is not really promoted by the institutes and authorities. Forcing researchers to use this tool would not be effective as it depends on sincere and wholehearted answers about the investigator's individual values. Involving an animal

welfare officer at the institute to improve the quality of evaluation proved more effective. However, this approach requires a certain degree of motivation and commitment on the part of the animal welfare officer.

3 Too much weight on natural science reasoning

A major reason for the harm-benefit analysis not being carried out according to the law in practice is the structure of the committee. It is clearly dominated by natural science reasoning. At least two thirds of its members, sometimes more, including representatives of animal welfare organizations, have a background in natural sciences.⁹ This kind of thinking is often in conflict with the questions raised by humanities or ethics in particular. The question “Are we allowed to do so?” is not a technical but a normative one. As such, natural science skills are not adjuvant and scientists are ill-equipped for this kind of question.

When it comes to ethical questions, scientists are confronted with a personal conflict of interests. They are not allowed to challenge science as an end in itself, whereas the assessment of every research objective including its accurate weighing is a major task of the harm-benefit analysis. For instance, scientists routinely insist on discriminating between different forms of human suffering being “unethical”, thus avoiding any discussion on why social phenomena – e.g., lack of concentration, aging, or menopause, to name a few – are considered diseases. This leads to the fact that whatever is considered a disease can in principle justify even the most severe interference with the integrity of experimental animals.

Nevertheless, the harm-benefit analysis demands the assessment of every aspect on both sides of the scale on a case-by-case basis. An improvement towards a serious implementation of balancing interests required by law could therefore be a two-stage or bicameral committee examination. Technical scientific questions and 3R considerations could be discussed separately from ethical issues such as indispensability and proportionality.

4 Harm-benefit analysis as part of the “essential measure”

A cardinal aspect in terms of evaluating interests often remains unattended: the harm-benefit analysis represents only one part of the “essential extent” (“*unerlässliches Mass*”)¹⁰. In this con-

⁷ Please note that in Zurich, animal experiments are carried out mainly by universities doing basic research. There is only little applied research by the industry (as there is, for example, in Basel).

⁸ This self-assessment tool is available on <http://tki.samw.ch/>.

⁹ Some Swiss cantons explicitly prescribe the composition of its animal experiment committee, e.g., Bern in article 9 of its Verordnung über den Tierschutz und die Hunde (THV) vom 21. Januar 2009 (systematic number 916.812): the committee compulsively covers the skills of physicians, veterinarians, pharmacists, biologists, ethologists, and scientists performing animal experiments. Additionally, two members of animal welfare organisations are part of the committee (without specifying their professional background). No ethical or comparable knowledge is required.

¹⁰ Art. 17 TSchG.

text, researchers prevalently tend to shift discussions to balancing interests which they expect to turn out in their favor because they are convinced of the important work they are doing for the benefit of mankind.¹¹

The proportionality (*Verhältnismässigkeit*) of a research project involving animals which has to be substantiated in the application consists of three stages: applicability (*Eignung*), necessity (*Erforderlichkeit*), and proportionality in a narrow sense, meaning evaluating and balancing interests. In practice, applicability and necessity are often underestimated by animal welfare representatives. Instead, the focus is on the harm-benefit analysis. Both applicability and necessity are mostly presumed as a matter of course, although there are weighty reasons against them. If these reasons are strong enough to raise reasonable doubts in the evaluating person about the applicability or the necessity of the respective experimental design, the harm-benefit analysis must take such doubts into account. If a proposal barely reaches the necessity threshold, its anticipated benefits must be discounted as speculative. Minimal harm should be enough to outweigh such benefits.

5 Improving the harm-benefit analysis

There have been many concepts and tools attempting to balance the seemingly unquantifiable interests of human benefit and animal damage and suffering (A very good overview is provided by Alzmann, 2010, p. 119ff). None of them could solve the problem of subjectivity regarding the measure of value. Besides, most of the suggested concepts cannot be applied to basic research projects.

From a rational perspective, the interests on the animal's side are weighty and most of them are absolutely essential to the individual concerned: harm includes damage, suffering, pain, anxiety, as well as impairments to their well-being in general,¹² e.g., constraints due to keeping and hindering them from displaying their natural behavior, furthermore intrusion into their dignity (which explicitly has to be considered in Switzerland), and their lives in a twofold meaning: their lives are meant to be a measuring instrument and death is included.

Of course, not every animal experiment causes all of the mentioned aspects of harm, but some do, and often many of the mentioned factors occur concurrently. The certainty of the anticipated harm compared to the speculative long-term benefit in basic research is another factor to take into account. Experimental designs in basic research create, at best, small pieces of knowledge on the long way to a benefit for humans.

A huge part of experiments is simply idling. Is the simple speculation that any one of these experiments might lead to important future findings weighty enough to overbalance the present harm?

6 Conclusion

The harm-benefit analysis can be a reasonable tool to take animals into account as sentient beings and set barriers to the boundless exploratory urge of science. Experience, however, has shown vast deficiencies in its implementation. A harm-benefit analysis reduced to the formal explanation that health benefits will hopefully be gained, together with the presumption that health benefits always outweigh animal suffering, is simply nonsense.

The focus has to be on strong and uncompromising enforcement – in the sense that the harm-benefit analysis must not just be devolved to an authority or a committee, taking away the responsibility from the legislator and society. Rather, the committee and the authority members should both be supervised and encouraged to make brave decisions which do not have to conform to the inept tradition of administrative practice. Science often aggrandizes itself and claims to be so essential that it must not be constricted by ethical limitations. This self-serving concept must be opposed.

Proportionality, including all three stages (applicability, necessity and harm-benefit analysis) must be examined more seriously. Decisions deriving from current practice must be reinforced as long as they are not arbitrary.¹³ As there is no panacea available for an analysis procedure conforming to the law and reflecting society's opinion, a two-stage assay or a bicameral committee could be an important step towards mitigating current bias.

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¹¹ In general, the requirement to show justification for animal experimentation, which is indisputably associated with a considerable amount of effort on the part of the applicants, is perceived as harassment.

¹² Art. 17 TSchG: erhebliche Beeinträchtigungen des Allgemeinbefindens.

¹³ The cantonal committee for animal experimentation in Zurich appealed against two cases involving non-human primates, which provoked notable disturbances within the scientific community. This can be explained by the fact that hardly any animal experiment has ever been refused on ethical grounds. The Supreme Court decisions, BGE 135 II 405; BGE 135 II 384, are published on <http://www.bger.ch>.



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- All application forms: <http://www.blv.admin.ch/themen/tierschutz/00777/00779/index.html?lang=en> (English); <http://www.blv.admin.ch/themen/tierschutz/00777/00779/index.html?lang=de> (German)
- (all internetpages last accessed on December 3, 2014).

Legal basis

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