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

– Evaluation Process for Animal Experiment Applications in Switzerland

Extended abstract to the Messerli Research Institute Symposium at the University of Veterinary Medicine Vienna, April 2013, by Vanessa Gerritsen, Foundation for the Animal in the Law (Stiftung für das Tier im Recht, TIR), Zurich (CH), gerritsen@tierimrecht.org

As Switzerland is not a member of the EU, the respective EU directive is not binding to Swiss authorities or the Swiss legislative power. The harm-benefit analysis, however, has been integral part of Swiss animal experimentation legislation for years. Hence, a certain practice has been established.

Severity Grades and Permitting Procedure

A severity grade catalogue[1], launched in 1995, divides every application for an animal experimentation project into four categories from 0 to 3. Severity degrees 1 to 3 are declared as burdensome to the animal, with degree 3 as comprising extremely severe tests, or moderately severe ones over a long time period. All experiments of degrees 1 to 3 are coercively examined by a cantonal committee for animal experimentation. It has an advisory function to the cantonal veterinary authority as the granting body.

Severity degree 0, meaning there is no pain, suffering, damage or anxiety inflicted on the respective animal, is authorised by the cantonal veterinary authority without mandatory comprehension of the cantonal committee for animal experimentation. It is worth mentioning that severity degree 0 comprises tests in which the animal is being killed painlessly to extract organs, tissue, cells etc. due to the legislator's opinion that death is not a kind of damage (this opinion is challenged in scientific literature)[2].

When applying for an animal experiment project, the researcher has to determine the expected degree for all animal groups undergoing burdensome manipulations, explaining in form A (application to perform animal experiments)[3] which animals are going to suffer in what sense and how much.

After the completion of the approved animal experiment or at the end of each year, the experimenter has to fill out form C (report on animal experiment)[4], re-evaluating the degree of every animal used, based on the facts and ongoings of the project. Corresponding criteria are defined in a further catalogue, focusing on the monitoring of behaviour parameters and signs of pain in different animal species.[5]

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[1] Bundesamt für Veterinärwesen BVET, Einteilung von Tierversuchen nach Schweregraden vor Versuchsbeginn (Belastungskategorien), Allgemeine Leitsätze und Beispiele zur analogen Klassierung weiterer Versuche, Information Tierschutz 1.04, available at www.bvet.admin.ch.

[2] Goetschel/Bolliger, 99 Facetten 215; Gerritsen/Rüttimann, Neue Wege 263.

[3] Form A: Application to perform animal experiments (V1.4), and respective explanatory notes. All forms are retrievable at www.bvet.admin.ch.

[4] Form C: Report on animal experiment (V1.3), and respective explanatory notes, see footnote 3.

[5] Bundesamt für Veterinärwesen BVET, Retrospektive Einteilung von Tierversuchen nach Schweregraden (Belastungskategorien), Information Tierschutz 1.05, available at www.bvet.admin.ch.

Harm-Benefit Analysis in Theory and Practice

In theory, legislation is clear,[6] and literature, both scientific and from animal welfare groups, agree: the infliction of pain, suffering, damage or anxiety to an animal must not be licensed if there is no *evidence* of a benefit *over*balancing[7] the animal's suffering. The severer the harm, the greater the need for justification:[8] The benefit has to be analogously more important, more realistic, and more promptly realisable.

The frequently cited *Ethical Principles and Guidelines for Scientific Animal Testing* of the Swiss Academies of Arts and Sciences state that some experimental designs presumably inflict pain or suffering classified as so severe that the harm-benefit analysis cannot be outweighed by a human benefit. If the design cannot be changed to alleviate the suffering, there is moral obligation to abstain from the experiment and the benefit hoped for.[9]

In practice – I am speaking as a member of the committee for animal experimentation of the canton of Zurich –[10] the aforementioned is not what is carried out. The harm-benefit analysis is reduced to a mere formal requirement, fulfilled by the experimenter by explaining that the meant project is able to contribute to the development of new therapies. Objections to an inadequate or insufficient evaluation of interests on the part of the committee for animal experiments are only raised in respect to formal deficiencies, e.g. if the researcher has failed to oppose the damage and suffering of the animal to the described benefit. As soon as this has been formally cleaned up, the committee no longer deals with this aspect. A real harm-benefit analysis or an examination of all interests concerned is not carried out by the committee or by the granting authority. It is seen as implicit that health benefits outweigh and overbalance the harm of 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 disposition regarding the actual project. Only in rare cases of poorly described experimental designs, projects are challenged with respect to the harm-benefit analyses and rejected, giving the researcher the option to thoroughly revise the application.

In respect to the applicants, the Swiss Academy of Medical Sciences and the Swiss Academy of Sciences established an online self-evaluating tool provided for researchers performing animal experiments.[11] The ethical assessment guide for conflicting issues in animal experimentation enables researchers to look into ethical questions in terms of the harm-benefit analysis. Constructed as a points rationing system, the researcher is asked to answer 29 questions about the expected benefit, including human health and quality of life, and health and welfare of animals as well as 3R contributions. On the cost/harm side, questions target grade of severity, species, number of animals used, expectation of further experiments involving animals, and 3R possibilities. A third category gauges the researcher's sense of responsibility.

Unfortunately, this voluntary tool seems to be used only in rare cases. Presumably, it is just not present in the scientists' minds as it is not really propagated by the institutes and the authorities. To force researchers to use this tool would not make any sense as it depends on sincere and wholehearted answers about the investigator's subjective values.

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[6] Art. 19 Abs. 4 TSchG.
[7] Art. 3 lit. a TSchG: *overbalancing* interests are required to justify harm inflicted upon animals.
[8] Akademien der Wissenschaften Schweiz 3; EKAH/EKTV 7f.; Zenger 118f.; Kley/Sigrist 37.
[9] Akademien der Wissenschaften Schweiz 3, paragraph 3.5.
[10] Please note that in Zurich, animal experiments are performed predominantly by universities doing basic research. There is only little applied research done by the industry (as for example in Basel).
[11] This self-assessment tool is available at http://tki.samw.ch/.

It has been shown as more promising to involve an institute's animal welfare officer to improve the quality of evaluation. An inalienable precondition, however, is a certain degree of motivation and commitment of the animal welfare officer.

Harm-Benefit Analysis as Part of the "Indispensable Limit"

A cardinal aspect in terms of the evaluation of interests often remains unattended: The harm-benefit analysis represents one part of the "indispensable limit" ("unerlässliches Mass")[12] only. In this context, researchers prevalently tend to shift discussions to the balance of interests which they expect to turn out in their favour because they are convinced of the important work they are doing to the benefit of mankind.[13]

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 the evaluation and balancing of interests. In practice, applicability and necessity are often underestimated by animal welfare representatives, and the focus is put on the harm-benefit analysis. Both applicability and necessity are mostly presumed as a matter of course, although there are weighty reasons against them. Even if these arguments are not corroborated but strong enough to cause reasonable doubt in the evaluating person about the applicability or the necessity of the respective experimental design, these doubts stringently have to influence the harm-benefit analysis. In this sense, the anticipated benefit is debilitated accordingly in comparison to the interests involved.

Improving the Harm-Benefit Analysis

There have been many concepts and tools trying to balance the imponderable interests of human benefit and animal damage and suffering.[14] None of them could solve the problem of subjectivity regarding the measure of value. Besides, most of the suggested concepts are not applicable to basic research projects.

Considered rationally, the number of interests on the animal's side weigh enormously and most of them are absolutely essential to the individual concerned: harm includes damage, suffering, pain, anxiety, but also impairments to their well-being in general,[15] e.g. constrictions due to their keeping and hindrance of displaying natural behaviour. Furthermore, intrusion into their dignity (which has to be considered explicitly in Switzerland), and their life in a double meaning: their whole life is 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 enumerated factors are concerned concurrently. The concreteness of the anticipated harm compared to the long term benefit in basic research is another facet to take into account. Experimental designs in basic research create, at best, small pieces of knowledge on the long way to a benefit for human kind. A huge majority of experiments are simply idling. Is the simple hope

[12] Art. 17 TSchG.

[13] In general, the justification for animal experimentation which is indisputably affiliated to a considerable amount of efforts on the part of the applicants prevailingly is seen as harassment.

[14] A very good overview is provided by Alzmann 119ff.

[15] Art. 17 TSchG: *erhebliche Beeinträchtigungen des Allgemeinbefindens*.

that any one of this high number of experiments might lead to important findings so weighty as to overbalance the concrete harm?

Conclusion

The harm-benefit analysis may be a reasonable tool to take animals into consideration as sentient beings and set barriers to the boundless exploratory urge of sciences. But experience has shown vast deficiencies in its implementation. A harm-benefit analysis reduced to the formal explanation that health benefits are hoped to be gained, conjoined with the presumption that health benefits always weigh heavier than animal suffering, simply is nonsense.

Focus has to be put on the enforcement without fail, in the sense that the harm-benefit analysis must not just be delegated to an authority or a committee, taking away the responsibility from the legislator and society. Rather, committee and authority members should be both supported and supervised to take *brave decisions* which do not have to be conform to the clumsy tradition of administrational practice. Science often aggrandises itself and claims to be essential enough that it must not be constricted by ethical limitations. This self-concept must be opposed.

The examination of proportionality, including all three stages (applicability, necessity and harm-benefit analysis), must be taken more serious. Decisions deviating from the current practice have to be strengthened as long as they are not arbitrary.[16]

Resources

Eidgenössische Ethikkommission für die Gentechnik im ausserhumanen Bereich (EKAH) und Eidgenössische Kommission für Tierversuche (EKTV), The Dignity of Animals, A joint statement by the Federal Ethics Committee on Non Human Biotechnology (ECNH) and the Federal Committee on Animal Experiments (FCAE), concerning a more concrete definition of the dignity of creation with regard to animals, Bern 2001 (cit. EKAH/EKTV)

Ethikkommission für Tierversuche der Akademien der Wissenschaften Schweiz, Ethische Grundsätze und Richtlinien für Tierversuche, 3. Auflage 2005 (cit. Akademien der Wissenschaften Schweiz)

Alzmann Norbert Gernot, Zur Beurteilung der ethischen Vertretbarkeit von Tierversuchen, Diss. Tübingen 2010

Gerritsen Vanessa / Rüttimann Andreas, Neue Wege im Tierversuchsrecht, Michel/Kühne/Hänni (Hrsg.), Animal Law - Developments an Perspectives in the 21st Century / Tier und Recht - Entwicklungen und Perspektiven im 21. Jahrhundert, Zürich/St. Gallen 2012, S. 239-269

Kley Andreas / Sigrist Martin, Güterabwägung bei Tierversuchen – Intentionen des Gesetzgebers und erste Anwendungen, in: Sigg Hans / Folkers Gerd (Hrsg.), Güterabwägung bei der Bewilligung von Tierversuchen, Die Güterabwägung interdisziplinär kritisch beleuchtet, Zürich 2011, S. 35-47

[16] The appeal, made by the cantonal committee for animal experimentation in Zurich in two cases involving non human primates, provoked notable disturbances within the scientific community. This is explained through the fact that hardly ever an animal experiment has been refused out of ethical reasons. The Supreme Court's decisions, BGE 135 II 405; BGE 135 II 384, are published at http://www.bger.ch.

Zenger Christoph Andreas, Das "unerlässliche Mass" an Tierversuchen, Ergebnisse und Grenzen der juristischen Interpretation eines "unbestimmten Rechtsbegriffs", Beihefte zur Zeitschrift für Schweizerisches Recht, Heft 8, Basel/Frankfurt a.M. 1989

Legal basis

Tierschutzgesetz vom 16. Dezember 2005 (TSchG), SR 455, available in German at http://www.admin.ch/ch/d/sr/c455.html

Tierschutzverordnung vom 23. April 2008 (TSchV), SR 455.1, available in German at http://www.admin.ch/ch/d/sr/c455_1.html

Verordnung des BVET vom 12. April 2010 über die Haltung von Versuchstieren und die Erzeugung gentechnisch veränderter Tiere sowie über die Verfahren bei Tierversuchen (Tierversuchsverordnung), SR 455.163, available in German at http://www.admin.ch/ch/d/sr/c455_163.html

Verordnung des EDI vom 5. September 2008 über Ausbildungen in der Tierhaltung und im Umgang mit Tieren, SR 455.109.1, available in German at http://www.admin.ch/ch/d/sr/c455_109_1.html

Jährliche Tierversuchsstatistik: http://tv-statistik.ch/de/statistik/index.php

Bundesamt für Veterinärwesen BVET: Formulare, Informationen und Richtlinien zum Tierversuchsbewilligungsverfahren:
http://www.bvet.admin.ch/themen/tierschutz/00777/03585/index.html?lang=de

All application forms:
http://www.bvet.admin.ch/themen/tierschutz/00777/00779/index.html?lang=en (English)
http://www.bvet.admin.ch/themen/tierschutz/00777/00779/index.html?lang=de (German)