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Workshop Report: Implementation of the 3Rs – Regulatory Animal Testing and Current Debates on Transparency in Animal Experimentation[1]

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Abstract

This workshop report summarizes the key findings and discussions of the event "Implementation of the 3Rs in Swiss Law – Regulatory Animal Testing and Current Debates on Transparency in Animal Experimentation", held in Zurich on 20 March 2025. The workshop brought together experts from academia, regulatory bodies, and NGOs to address two key issues in animal research: regulatory chemical safety assessments and transparency as a legal requirement.

Keywords

Regulatory Animal Testing, 3Rs, Transparency, Animal Experimentation, Chemical Safety Assessment

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I. Introduction

On 20 March 2025, Prof. Dr. Margot Michel and her team from the research project "Implementation of the 3Rs in Swiss Law" as part of the National Research Program "Advancing 3Rs – Animals, Research and Society" (NRP 79)[2] held a workshop in Zurich on the topic of „Implementation of the 3Rs – Regulatory Animal Testing and Current Debates on Transparency in Animal Experimentation". The workshop brought together various stakeholders from academia, administrative authorities, and NGOs to explore the current state and future direction of animal experimentation regulation in Switzerland and beyond, emphasizing regulatory chemical safety assessments and transparency as a legal requirement.

Prof. Dr. Margot Michel provided an overview of the overarching project situated within the framework of the National Research Programme 79 (NRP 79), which forms the contextual foundation of the workshop and guided the selection of its thematic focus areas. She also introduced the three sub-projects and the respective team members responsible for their implementation.

The project is based at the University of Zurich's Faculty of Law and is dedicated to examining the 3Rs principle – *Replacement, Reduction, and Refinement* – from a legal perspective. It examines how the legal framework regulates animal experimentation and explores potential avenues for legal reform to more effectively promote the implementation of the 3Rs.

The **first sub-project**, conducted by M.A. Nicole Lüthi, analyses the similarities and differences between the regulatory frameworks for human research and animal experimentation. The aim is to identify opportunities for greater harmonization between the two areas. This comparative analysis lays the groundwork for a more in-depth examination of legal issues that intersect these two fields, emphasizing transparency requirements – an increasingly important issue not only in Switzerland but across Europe.

[2] <NRP 79 –Animals, Research and Society | Rechtswissenschaftliche Fakultät | UZH> (accessed on 2 April 2025).

The **second sub-project**, carried out by lic. iur. Katerina Stoykova, focuses on regulatory animal testing – testing required by law to ensure public safety. This sub-project examines the potential for advancing and implementing more effective 3Rs provisions in this area. Central to this investigation are the capacities and limitations of legislation to facilitate a transition toward an animal-free regulatory system, particularly in chemical safety assessment. Special attention is paid to the implicit legal barriers to the adoption of non-animal New Approach Methodologies (NAMs).

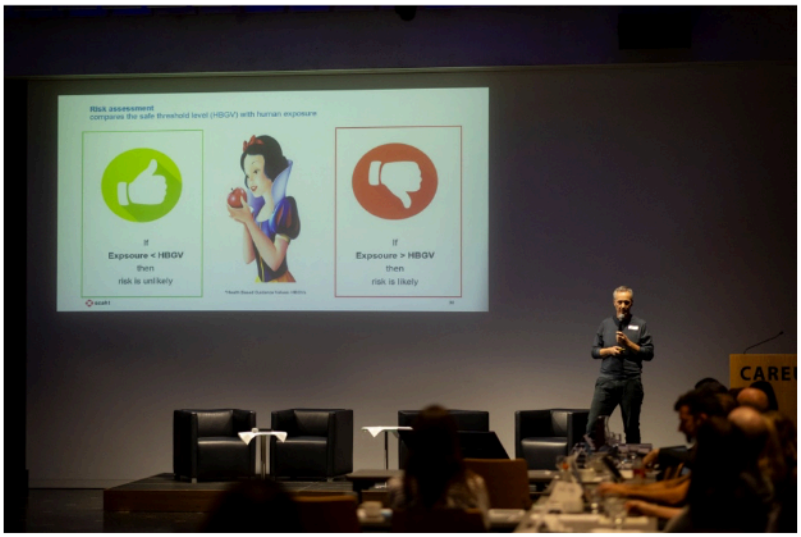
The **third sub-project**, implemented by ass. iur. Sara Faizee, is a recently launched initiative (as of early 2025) entitled *"Bringing Law to Life",* which was not included in the workshop due to its novelty. This sub-project is designed as an innovative, implementation-oriented initiative that aims to bridge the gap between the legal field and the natural sciences, as well as other disciplines within the humanities. It is based on the idea that existing legal frameworks have untapped potential to advance the 3Rs, and that interdisciplinary collaboration is essential to unlock this potential in practice.

II. Thematic Block 1: Regulatory Animal Testing

Lic. iur. Katerina Stoykova introduced the first session on regulatory animal testing with a focus on chemical safety assessment, touching on the various challenges of moving towards non-animal chemical safety assessment. She also highlighted the political intent and endeavours within the European Union to move away from animal-based chemical safety testing, as well as Switzerland's responsibility to promote the 3Rs beyond its borders.

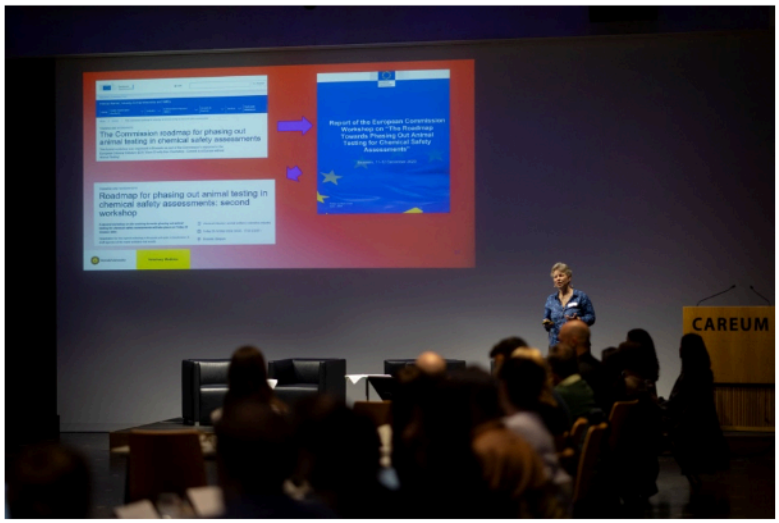
The first thematic block consisted of three presentations, namely by Dr. Lothar Aicher (regulatory toxicologist with the Swiss Center for Applied Human Toxicology, SCAHT), Prof. Dr. Merel Ritskes-Hoitinga (professor in Evidence-Based Transition to Animal-free Innovations at Utrecht University in the Netherlands) and Dr. Markus Hofmann (deputy head of the REACH & Risk Management Section at the Swiss Federal Office of Public Health).

Dr. Lothar Aicher offered insights into the field of regulatory toxicology, explaining its aim of establishing safe threshold levels for chemicals and the risk assessment process, which consists of several important steps, such as identifying a chemical's hazard and estimating the exposure to a chemical to assess its likelihood of having an adverse effect. He explained that animal studies are still at the forefront of human safety testing because of their ability to examine the response of complex living organisms to different dose levels of a substance – a practice still often considered essential in toxicology. That said, he underscored the limitations of an animal-based approach – particularly the impossibility to test some 100'000 still untested chemicals on animals in a timely manner – and called for a paradigm



shift towards human-based risk assessment. Dr. Aicher highlighted that while traditional animal testing has long been the standard for hazard identification, it is extremely costly, slow, and limited in scope. He also explained how traditional testing methods do not reflect real-world exposure to chemicals and argued for broader adoption of New Approach Methodologies (NAMs). Dr. Aicher concluded that political, legal, and scientific hurdles such as outdated validation requirements and initial scepticism about (non-animal) NAMs, must be overcome to enable a true transition to a non-animal next-generation risk assessment. Finally, he emphasised that we must achieve "more with less" both to ensure human safety and reduce the use of animals.

Prof. Dr. Merel Ritskes-Hoitinga presented recent developments at the EU level, including the current developments on the Commission's roadmap to phase out animal testing for chemical safety assessment, and highlighted the importance of transition science in achieving systemic change. Transition science focuses on how complex systems shift over time, and how niche innovations such as NAMs can be scaled up to replace "traditional" practices like animal experimentation. Prof. Ritskes-Hoitinga also called for increased funding for the development, and most importantly, the validation of NAMs, comprehensive legal reforms to enable non-animal approaches, and improved coordination between EU member states. She also stressed that legislative change is essential, as current legal frameworks are deeply rooted in an animal-based testing paradigm, which impedes the potential for implementation of NAMs and makes it difficult for regulators to accept NAMs-based data. She highlighted three main challenges to the implementation and regulatory acceptance of NAMs. First, she pointed out that the value of NAMs is often not known, recognized, or accepted, particularly by regulators, leading to a lack of confidence and trust. Secondly, she noted that funding is needed to support the validation, implementation, and acceptance of NAMs, as current financial resources are often insufficient. Finally, she identified the lack of global harmonization and mutual recognition as a major barrier. Prof. Dr. Ritskes-Hoitinga emphasized that systematic reviews and/or evidence synthesis could significantly accelerate the process of implementing NAMs by providing objective and transparent evidence of their reliability and relevance



Dr. Markus Hofmann presented Switzerland's active role in advancing the development and validation of NAMs through its engagement in the OECD Test Guidelines Programme. He highlighted the successful validation and regulatory use of several 1:1 non-animal replacements of traditional animal-based toxicity tests for simple endpoints (e.g. in vitro methods for skin corrosion/irritation) and of Defined Approaches for skin sensitisation (full replacement data packages based on *in vitro* and *in silico* methods). At the same time, he stressed the need for further work on the development and validation of new approaches that can be applied to more complex endpoints such as chronic or systemic effects in the human organism, or test batteries and systems that generate large amounts of data and allow high throughput to address the growing need for information. Dr. Hofmann emphasised that achieving full regulatory integration of NAMs will require enhanced international coordination, strong commitment from all parties involved and targeted funding for the critical regulatory acceptance steps (e.g. validation, independent peer reviews).

III. Thematic Block 2: Transparency (with Special Consideration of "Surplus Animals")

M.A. Nicole Lüthi opened the second thematic block on transparency in animal experimentation, highlighting the importance of transparency in this context and its role as a fundamental prerequisite for the rule of law and democracy, as it enables the public to monitor government actions and strengthens democratic legitimacy. She also emphasized that transparency is essential to ensure the integrity and quality of scientific research, and to assess whether the 3Rs principles are being effectively applied.

This was followed by three presentations on the topic of transparency in animal experimentation, namely by Dr. Vanessa Gerritsen (Executive Board Member, Foundation for the Animal in the Law (Stiftung für das Tier im Recht (TIR); former member of the Animal Experimentation Committee Zurich), Dr. Otto Maissen (Head of Animal Experimentation, Federal Food Safety and Veterinary Office), and Dr. Barbara Felde (Vice Chair, Deutsche Juristische Gesellschaft für Tierschutzrecht; judge at the Administrative Court Giessen).

Dr. Vanessa Gerritsen outlined critical gaps in public access to meaningful information on animal experimentation in Switzerland. Despite existing legal obligations, significant barriers remain. Vanessa Gerritsen stressed that current reporting practices – mainly statistical overviews – fail to inform citizens about the lived realities of animal research. She proposed clearer communication strategies, including case-level reporting and more accessible summaries, pointing to more progressive models such as those in Norway.

She also pointed out that this lack of transparency is particularly paradoxical given the strict legal framework for animal research in Switzerland. On the one hand, the constitutional protection of laboratory animals is so extensive that it justifies severe restrictions on fundamental rights, such as the guarantee of property, freedom of research, and economic freedom. On the other hand, private economic interests and trade secrets often prevent access to relevant information, even though these interests would not constitute a legitimate basis for conducting animal experiments. This contradiction not only undermines public oversight and democratic accountability but also slows down scientific progress and may even lead to redundant or repeated experiments, which conflicts with the legal principle of indispensability. Dr. Gerritsen explained that this lack of transparency also applies to funding. Namely, public institutions for research funding neither disclose nor monitor how much money is spent on animal testing. This makes it impossible for the public to compare how much public funding is allocated to animal testing and how much to NAMs-based research and testing.

Dr. Otto Maissen elaborated on the legal foundations for transparency in animal experimentation, defining transparency as "access to proper and relevant information". While certain elements of transparency are already in place, he recognized that they are often difficult to navigate and not user-friendly. Nevertheless, he acknowledged progress, and announced that by the end of the year, data on animal experimentation is expected to be available on the dashboard of the Federal Food Safety and Veterinary Office (FSVO) in the form of easy-to-read graphs, with the full raw data available on the "opendata.swiss" platform. The aim is to significantly improve accessibility and usability, while at the same time respecting data protection principles. Transparency, he explained, has already had some tangible effects: the publication of statistical data has sparked public debate, which in turn has influenced legislative developments. However, given the public's increasing demand to understand animal research, more information on animal experimentation needs to be published. To this end, Dr. Maissen presented various solutions, such as the publication of non-technical project summaries, the possible pre-registration of animal studies or, more generally, the expansion of the publication requirements under Art. 20a AniWA (SR 455). These options are currently being examined by the FSVO.

Dr. Barbara Felde provided a comparative perspective from Germany, focusing on the under-reported issue of "surplus animals", i.e. laboratory animals that are bred for research but ultimately not used. She argued that killing such animals without a scientifically justified purpose may violate the German Animal Welfare Act, which implements the EU Directive 2010/63/EU at the national level. Dr. Felde sees a major problem in the use of the vague legal term "reasonable cause", which is sometimes interpreted too broadly or sometimes arbitrarily, leading to normative uncertainty. Since 2021, the German Federal Institute for Risk Assessment (BfR) has been overseeing transparency in this area, and, in 2023, established that the killing of animals must be justified on a case-by-case basis. However, transparency remains limited, and the issue of surplus animals illustrates the deep tension between legal standards and institutional practice.

IV. Discussions and Exchange

Following the presentations, the workshop participants engaged in a meaningful and insightful dialogue, bringing together many different perspectives and positions. In the discussion rounds, speakers and participants explored individual issues in depth, exchanged perspectives, and highlighted current problems as well as opportunities for improvement. The discussions underlined the pressing need for a more rigorous implementation of the 3Rs and highlighted the need for precise legal definitions, enhanced cross-sectoral collaboration, and international harmonization as key drivers for substantial improvements in research practices.