News

AUT: Austrian Animal Protection Law demands cost-benefit analysis

From mid-2016 applications to perform animal experiments will have to include a completed "criteria catalogue." That is one of the few improvements included in the new Austrian Animal Protection Law, which came into force at the beginning of the year. The aim of the criteria catalogue is to objectify the cost-benefit analysis, which is demanded as an obligatory component of the evaluation process by Directive 2010/63/EU. The cost-benefit analysis weighs the pain, distress, and suffering the animals will be subjected to against the expected benefits that could result from the experiments. The criteria catalogue shall help applicants and competent authorities to perform the balance of interests by increasing objectivity and transparency of the evaluation procedure.

As Switzerland is the only country that currently has a criteria catalogue that allows rejection of an application to perform an animal experiment on ethical grounds, such a legally binding criteria catalogue could have been a big step forward for Austria. The Austrian Animal Protection Law, however, specifically does not prescribe this criteria catalogue to be instated at ordinance level, only that it be published. Therefore it will have no legal impact.

An enforceable implementation of a criteria catalogue would be difficult in light of the constitutional framework: The basic right to scientific freedom stands against the rejection of an application to perform an animal experiment on ethical grounds. Therefore it is to be expected that in the end even grave ethical concerns will not lead to the rejection of any animal experiment. Finally, the law's wording on completing the criteria catalogue and submitting it with the application suggests that the complex process of a balancing of interests will be reduced to filling in a further checklist.

pem

EU: Final ban on animal experiments for cosmetic ingredients implemented

As announced on January 30, 2013 by European Commissioner for Health and Consumer Policy Tonio Borg, the final ban on marketing cosmetics containing ingredients tested in animal experiments entered into force on March 11, 2013 when the Commission communicated to the European Parliament and the Council that it had decided not to propose any changes to the animal testing related provisions in Directive 76/768/EEC (Cosmetics Directive) and Regulation 1223/2009/EC (Cosmetics Regulation).

Animal testing of finished cosmetic products in the EU has been banned since 2004 and of cosmetic ingredients since March 2009. Since March 2009 it has also been prohibited to market in the EU cosmetic products and their ingredients which have been tested on animals (also outside the EU) in order to meet the requirements of the Cosmetics Directive. Exceptions have been the testing of the endpoints repeated-dose systemic toxicity, skin sensitization, carcinogenicity, reproductive toxicity, and toxicokinetics, for which the marketing ban had been extended to March 11, 2013 to allow time for the development and validation of respective alternative methods.

A comprehensive technical report (Adler et al., 2011) indicated that none of these endpoints would be fully replaced by March 2013, and this was confirmed by a further report published in ALTEX (Hartung et al., 2011). An impact assessment directed at the stakeholders in European Member States to establish the possible consequences of the ban

showed divergent viewpoints and uncertainty regarding the impacts of the ban. In October 2012 the European Coalition to End Animal Experiments (ECEAE) handed a petition with almost 250,000 signatures gathered in their No Cruel Cosmetics campaign to the EU petitions committee.

In its Communication (EC, 2013) the Commission deemed that human health would not be impacted by the ban as products for which safety cannot be demonstrated cannot be placed on the market. This would be supported by new tools such as enhanced market surveillance and new rules on communication of serious undesirable effects in the Cosmetics Regulation, which will repeal and replace the Cosmetics Directive in July 2013. It argued that further postponements of the 2013 marketing ban would not reflect the political choices of the European Parliament and the Council when adopting the respective provision and that they would seriously diminish the determination to swiftly develop alternative test methods.

Data from animal testing that was carried out before the respective implementation dates of the marketing ban can continue to be used in the safety assessment of cosmetic products. Therefore, cosmetics and their ingredients that are already on the market and for which the safety is already established are not affected by the ban and can continue to be placed on the market. However, the majority of new ingredients that go into cosmetics are ingredients that are also in use in many other consumer and industrial products, such as in pharmaceuticals, detergents, food, paints, etc. These may therefore be subject to animal testing requirements under these respective legal frameworks.

sva

References

Adler, S., Basketter, D., Creton, S., et al. (2011). Alternative (non-animal) methods for cosmetics testing: current status and future prospects – 2010. *Arch Toxicol 85*, 367-485.

EC – European Commission (2013). Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics. http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/

Hartung, T., Blaauboer, B. J., Bosgra, S., et al. (2011). An expert consortium review of the EC-commissioned report "alternative (Non-Animal) methods for cosmetics testing: current status and future prospects – 2010". *ALTEX 28*, 183-209.

EU: EPAA review on 2R methods for reproductive toxicity in industry published

The European Partnership for Alternative Approaches to Animal Testing (EPAA) has published the second part of its survey on the use of alternative methods for reproductive toxicity in industry. While the first part of the survey, published in 2011, dealt with non-animal methods, the second part covers Reduction and Refinement of *in vivo* methods used either as stand-alone methods or as a part of Integrated Testing Strategies.

The survey is based on responses from only 10 companies, one of which is a contract research laboratory. It covers mainly chemicals and pharmaceuticals, with some information on cosmetics and animal health. Overall the survey indicates that screening and ranking of substances is done in the most part with non-animal methods and that *in vivo* methods are often used only as last tier options of Integrated Testing Strategies. Testing for regulatory purposes however often requires *in vivo* tests. The main strategies used to reduce and refine these tests were listed as "using reproductive toxicity data from repeated dose studies (e.g., histopathological examination of reproductive tissues) to render higher tier testing unnecessary, to carefully evaluate the need for the second generation in OECD 416 studies or to apply the new guideline OECD 443 (EOGRTS), to use the OECD 422 (combination of a repeated dose study with a reproductive/developmental toxicity screening test) instead of separate repeated dose and reproductive/developmental toxicity screening tests, and to take advantage of the flexibility that the ICH S5 guidelines offer (e.g., by reducing the number of animals used for satellite studies)."

The summary report is available online at: http://ecvam-dbalm.jrc.ec.europa.eu/ (Method Search/Topic Summaries) or http://ec.europa.eu/enterprise/epaa/index_en.htm

sva

GER: Grant program on alternatives to animal experiments

The State of Baden Württemberg is calling for grant applications for its program on alternatives to animal experiments by May 15, 2013. The state government aims to significantly reduce the number of animals used for experiments and the severity of procedures they are subjected to. € 400,000 is available in 2013 to support projects on the development of replacement and complimentary methods to animal experiments. This year projects on the development of 3Rs methods, projects on the ethical evaluation of animal experiments, and scientific approaches to develop animal-free educational programs in the life sciences may apply for funding.

Contact:
Dr Pyczak (Tel: +49 711 1262162)
or poststelle@mlr.bwl.de

Adapted from
Ministry for Rural Affairs
and Consumer Protection
Baden Württemberg
Press release 40/2013

GER: Marcel Leist and Stephan Reichl receive Felix Wankel Animal Protection Research Prize

On April 11, 2013 the Felix Wankel Animal Protection Research Prize was awarded equally to Marcel Leist, Doerenkamp-Zbinden Chair for *in vitro* toxicology and biomedicine in Konstanz, for his work on *in vitro* test systems for safety testing of chemicals with regard to reproductive toxicity and to Stephan Reichl, Institute for Pharmaceutical Technology, Technical University of Braunschweig, for his work on artificial tissues as *in vitro* drug absorption models and contributions to the reconstruction of the ocular surface. Both scientists received the award with prize money of € 15,000 each at a ceremony held in Munich.

The Felix Wankel Animal Protection Research Prize was founded in 1972. It is generally awarded every two years by the Ludwig Maximilians University in Munich for exceptional experimental and innovative scientific work aiming to or resulting in replacing or reducing animal experiments, improving animal protection, ensuring animal-appropriate housing of experimental, agricultural or companion animals, or supporting basic research to improve animal protection.

sva

GER: Call for applications for research prize on alternative methods

The Federal Ministry for Food, Agriculture and Consumer Protection calls for applications for its € 15,000 Animal Protection Research Prize, which will be awarded for the 32nd time later this year.

The prize will be awarded for scientific contributions to the development of pharmacological-toxicological testing approaches, such as for determination of acute, subchronic, or chronic toxicity, for mutagenic or cancerogenic properties or for reproductive and developmental toxicity and as well as for pharmacological activity. The implications of the results for humans should also be considered.

Applications must be submitted by April 30, 2013 and include only manuscripts that are in press or have been published within the past two years.

More information: http://www.bmelv.de/SharedDocs/Downloads/Ministerium/Ausschreibungen/32TierschutzforschungspreisAusschreibung.html

BMELV, January 9, 2013

GER: Animal ethicist Ursula Wolf receives research prize

For her outstanding and diverse research the philosopher Prof. Dr Ursula Wolf received the Meyer-Struckmann Prize for practical philosophy. Dr Wolf's research interests lie in the areas of analytical philosophy, ancient philosophy, action theory and applied ethics. Her early publications on animal ethics made her the best known animal ethicist in the German-speaking countries. Her book *Das Tier in der Moral* was published in 1990. Her current publication *Ethik der Mensch-Tier-Beziehung* discusses the past two decade's progress in ethics of the human-animal relationship.

Endowed with € 20,000, the prize was awarded to Dr Wolf, who is a member of the editorial board of *TIERethik* on November 14, 2012 at the Heinrich-Heine University in Düsseldorf, Germany.

pem

SUI: Egon Naef Foundation Research Prize for Luc Stoppini

On January 19, 2013 the Prize of the EgonNaef Foundation (FondationEgonNaef pour la Recherche in Vitro) was awarded to Prof. Dr Luc Stoppini. The award presentation took place at the Hotel Royal Manotel, Geneva, Switzerland.

Stoppini has developed several *in vitro* models to study the effects of chemical compounds on cellular physiology. This work entails the design of micro-engineered chambers in which human cells can be grown, differentiated into different cell types (liver, kidney, brain), and their activity recorded as precisely as possible. One of the most remarkable achievements of Stoppini was to design chambers in which nerve cells are grown directly on micro-electrodes that can monitor their electric activity. In this setup, the response of neural cells to chemical compounds can be determined rapidly and precisely. Stoppini has also developed more refined networks of chambers, in which different cell types can be grown in connected chambers, reconstituting partly the complex relationships between different organs in a human organism.

These remarkable technological advances have immediate applications in the field of toxicology. Use of *in vitro* assays on human cells may advantageously replace animal testing and thus significantly reduce the number of animals used for toxicological testing. These new technologies will also facilitate the discovery of new drugs.

At the same ceremony, the second price of the Foundation was awarded to Dr Marion le Coadic for her thesis work demonstrating that the crustacean *Daphnia magna* represents an alternative to animals to test the pathogenicity of bacteria.

Prof. Dr Pierre Cosson
Doerenkamp-Naef Chair
Centre Medical Universitaire
1 rue Michel Servet
1211 Geneva 4, Switzerland
Pierre.Cosson@unige.ch

UK: Chair for Animal Replacement Science announced

The Dr Hadwen Trust (DHT) and Queen Mary's University of London have joined forces to promote the global development of human-relevant methods and alternatives to animal use in diverse areas of bio-medical research. The DHT is to fund the first Professorial Chair in animal replacement science thanks to a £ 1 million legacy left to the DHT specifically for this purpose by lifelong supporter Alan Stross.

The successful applicant will be based at Queen Mary's Blizard Institute – a recognized pioneer in the development of *in vitro* models using human cells and tissue and in particular the development of three-dimensional models in cutaneous (skin), gastroenterology, and cancer research.

Applications for the DHT Professorial Chair in Animal Replacement Science at the Blizard Institute, Queen Mary will be invited shortly.

Adapted from Dr Hadwen Trust
science e-bulletin
January 17, 2013

UK: 3Rs Prize awarded to Donald Ingber for lung-on-a-chip device

The NC3Rs annual prize for an original contribution to scientific and technological advances in the 3Rs in medical, biological, or veterinary sciences published within the last three years was awarded to Professor Donald Ingber. Sponsored by GlaxoSmithKline, the prize consists of a grant of £ 18,000, plus a personal award of £ 2,000. Highly commended entries receive a £ 4,000 grant and £ 1,000 personal award.

Professor Donald Ingber's research, published in Science Translational Medicine, describes an innovative "lung-on-a-chip" microdevice that can accurately replicate conditions in a diseased human lung, offering a viable alternative to using animals in preclinical drug testing. The microdevice contains hollow channels lined with living human cells, mimicking both the interface between tissues and the unique physical environment seen in whole living organs. Crystal clear and flexible, it is approximately the size of a USB memory stick.

Applying a vacuum to part of the microdevice allows it to "breathe", recreating the way in which our tissues physically expand and contract during respiration. In testing it was able to successfully replicate the conditions seen in pulmonary oedema (fluid accumulation in the lungs), and predict results of a new drug for this life-threatening condition, which showed benefit in animal studies.

In addition, the microdevice has allowed the researchers to carry out real-time high resolution imaging on the cells and make accurate measurements of fluid flow and blood clot formation, which are not easily available in an animal model.

In their paper the researchers describe how the next step is to apply the technology to other human organs with the goal of one day being able to use it as part of an automated system to test many drugs. While it is not expected to offer an immediate replacement for animal studies, further development and applications of the technology could allow for a more gradual replacement of animal models of human disease.

Huh, D., Leslie, D. C., Matthews, B. D., et al. (2012). A human disease model of drug toxicity-induced pulmonary edema in a lung-on-a-chip microdevice. *Science Translational Medicine 4*, 159ra147.

Adapted from NC3Rs Newsletter
Issue 51 February 2013

USA: Martin L. Stephens receives SoT Enhancement of Animal Welfare Award

Martin L. Stephens, PhD, was awarded the 2013 Society of Toxicology Enhancement of Animal Welfare Award, becoming the third member of CAAT to receive the honor. Alan Goldberg and Thomas Hartung were earlier recipients. Dr Stephens is a senior research associate at the CAAT, where he coordinates the Center's activities on evidence-based toxicology. Prior to joining Hopkins in October 2011, Dr Stephens was vice president for animal research issues at The Humane Society of the United States where he directed the Society's efforts on behalf of animals in laboratories. He served on the National Academy of Sciences committee that wrote *Toxicity Testing in the 21st Century: A Vision and a Strategy*, as well as on program committees for the World Congresses on the use of animals and alternatives in the life sciences. He co-founded the Human Toxicology Project Consortium, which seeks to accelerate the implementation of pathway-based toxicity testing. Dr Stephens has received the Doerenkamp-Zbinden Award and the CAAT Recognition Award for his contributions to animal protection and alternative methods.

Posted on altweb.jhsph.edu/
March 21, 2013