News

AUT: Awards presented at the LINZ/EUSAAT 2012 Congress

The following awards were presented at the social event of the LINZ/EUSAAT 2012 Congress:

Two EUSAAT Poster Prizes: Award Document and € 250
Pre-validation of a High-throughput Reporter Gene Assay to Detect Genotoxicity and Oxidative Stress
A. R. M. von Bergh[1], S. C. van der Linden[2], B. Lussenburg[2], L. Jonker[2], M. Teunis[1], C. A. M. Krul[1], and B. van der Burg[2]
[1]*Innovative Testing in Life Sciences and Chemistry, Research Centre Technology & Innovation, University of Applied Sciences Utrecht, Utrecht, The Netherlands;* [2]*BioDetection Systems BV, Amsterdam, The Netherlands*

Applicability of *In Vitro* Test Strategies for Skin Irritation to Regulatory Classification Schemes: Substantiating Test Strategies with Data from Routine Studies
S. N. Kolle[1], K. Sullivan[2], A. Mehling[3], B. van Ravenzwaay[1], and R. Landsiedel[1]
[1]*BASF SE, Ludwigshafen, Germany;* [2]*Physicians Committee for Responsible Medicine, Oakland, CA, USA;* [3]*BASF Personal Care and Nutrition GmbH, Düsseldorf, Germany*

4-Pfoten/4-Paws Poster Prize: Award Document and € 250
Development of the EpiOcular™ Eye Irritation Test for Hazard Identification and Labelling of Eye Irritating Chemicals in Response to the Requirements of the EU Cosmetics Directive and REACH Legislation
Y. Kaluzhny[1], H. Kandarova[2], L. d'Argembeau-Thornton[1], P. Hayden[1], and M. Klausner[1]
[1]*MatTek Corporation, Ashland, MA, USA;* [2]*MatTek In Vitro Life Science Laboratories, s.r.o., Bratislava, Slovakia*

ALTEX Award 2012 for the best article published in 2011
Current standing and future prospects for the technologies proposal to transform toxicology testing in the 21st century. *ALTEX 28*, 17-44.
E. van Vliet
CAAT Johns Hopkins University Baltimore, MD, USA; currently Hospital Clinic – Universitat de Barcelona, Department of Maternal-Fetal Medicine, Fetal and Perinatal Medicine Research Group, Barcelona, Spain

EU: New Biocides Regulation enters into force

The Biocidal Products Regulation adopted by the Council and Parliament in the spring entered into force on July 17, 2012. The regulatory requirements for industry will apply from September 1, 2013 and ECHA is preparing to start the new regulatory processes by that date.

The new regulation sets rules for placing biocidal products on the market. The aim is to simplify and harmonize the procedures for authorization and at the same time ensure a high level of protection of human health and the environment. As under its predecessor, the Biocidal Products Directive, only biocidal products with approved active substances may be authorized to be placed on the market. A new element in the new regulation is the Union Authorisation, allowing companies to get an authorization for their biocidal products applicable across the whole EU.

The development of tools, processes and guidance will take full advantage of the synergies with REACH and CLP processes, which will make them easier to use for the stakeholders.

ECHA's task will be to coordinate the approval processes of biocidal substances and authorization of biocidal products at the Union level. A new Biocidal Products Committee, consisting of representatives from each of the EU Member States will give its opinion on biocidal products. ECHA will also provide technical and scientific support to the industry and Member States through IT tools, guidance and the helpdesk service.

Further information: http://echa.europa.eu/regulations/biocidal-products-regulation

Adapted from ECHA/PR/12/21
Press release of July 18, 2012

ALTEX recently published a t[4] report on the biocides regulation:
Ferrario, D. and Rabbit, R. R. (2012). Analysis of the proposed EU Regulation concerning biocide products and its opportunities for alternative approaches and a toxicology for the 21st century. *ALTEX 29*, 157-172.

EU: Kick-off of the Evidence-based Toxicology Collaboration Europe

The Evidence-based Toxicology Collaboration (EBTC) Europe held its official kick-off meeting on June 17, 2012 in conjunction with the 48th EUROTOX congress in Stockholm, Sweden. Inspired by the approaches defining Evidence-based Medicine/Health Care, the EBTC is a collaboration of individual scientists interested in applying and establishing evidence-based approaches in safety sciences. The EBTC's overall aims are to improve toxicological decision-making, facilitate the modernisation of the toxicological toolbox, and reinvigorate the safety sciences. As these efforts succeed, all interested parties should have greater confidence and trust in the process by which scientific evidence is assessed when addressing questions related to the safety of chemicals to human health and the environment. The Collaboration has closely coordinated steering committees in the US and Europe with members* drawn from government agencies, academia, and industry (see http://www.ebtox.com):

Sonja Beken (FAMHP)
Alan Boobis (Imperial College)
Neil Carmichael (ECETOC)
Barry Hardy (Douglas Connect)
Thomas Hartung (CAAT)
Jan Hengstler (Leibniz Research Centre)
Sebastian Hoffmann (seh consulting + services)
Philippe Hubert (INERIS)
Joanna Jaworska (P&G)
Ian Kimber (University of Manchester)
Annette Kopp-Schneider (Cancer Research Centre)
Marcel Leist (University of Konstanz)
Jean-Roch Meunier (L'Oréal)
Bennard van Ravenzwaay (BASF)
Kai Savolainen (Institute of Occupational Health)
Thomas Singer (Hoffmann-La Roche)
Nigel Skinner (Agilent)
Carl Westmoreland (Unilever)
Martin Stephens (CAAT, US EBTC liaison)
* affiliations for identification purposes only

The role of the steering committees is to promote the EBTC, give guidance and set the first working priorities. With the European steering committee being operational since the beginning of 2012, the kick-off was intended as a formal initiator of the work in Europe.

The meeting was opened by Dr Thomas Hartung, who holds the Doerenkamp-Zbinden Chair for Evidence-based Toxicology at the Johns Hopkins University Bloomberg School of Public Health. He provided an overview on Evidence-based Toxicology, reviewing the first ideas and the founding of the EBTC in the US. Dr Martin Stephens, the secretariat of the US EBTC steering committee sponsored by the Johns Hopkins Center for Alternatives to Animal Testing (CAAT), presented the ongoing work in the US.

Two steering committee members shaped the central presentation block by sharing their expectations on the EBTC and their motivation to contribute to EBTC. Dr Richard Judson from the US Environmental Protection Agency and member of the US steering committee discussed the need for new assessment methods for High Throughput Screening (HTS). In his view, evidence-based approaches focusing on the purpose and the mechanistic relevance of the assays could provide an efficient way to a sound assessment of HTS. Dr Thomas Singer, global head of non clinical safety of F. Hoffmann-La Roche Ltd and member of the European steering committee, emphasized the need for a paradigm shift in safety assessments from the traditional observational and descriptive approach to a predictive approach being mechanistic and translational.

The final set of presentations was dedicated to two proposals that could be potential priorities for the work of the EBTC in Europe. Dr Mardas Daneshian of the CAAT Europe summarised an ongoing effort to propose quality standards for publications dealing with *in vitro* test systems. Such standards could results in publications of a structure and completeness that would make them more amendable for systematic review, the central evidence-based tool. Dr Sebastian Hoffmann, seh consulting + services and secretariat to the European branch, elaborated on parallels between toxicological test assessment and (evidence-based) diagnostic test assessment. These parallels suggest that methodologies and tools used in diagnostic test assessment could be adopted or adapted to toxicological tests.

In the closing discussions participants were especially interested in the next steps of the EBTC. Dr Hartung explained that the European steering committee will define work priorities similar to the ongoing process in the US. Depending on the nature of these priorities, working groups to either produce guidance or case studies will be established. It was stressed that the EBTC is open for any interested scientist. The level of involvement can range from observation (e.g., through a newsletter) to active participation in working groups. Further information can be found on the EBTC website: http://www.ebtox.com

Sebastian Hoffmann
Secretariat to European EBTC steering committee
June 17, 2012

EU: ECHA statement on minimizing animal testing under REACH

REACH strikes a balance between the need of information to increase our understanding of the hazards of chemical substances, and the aim of avoiding unnecessary testing on animals in generating such information. New tests may only be carried out when all other sources of data have been exhausted. Vertebrate animal testing under REACH is only possible as a last resort.

For many substances, information on properties such as organ toxicity after long term exposure to chemicals, the potential to induce cancer, the toxic damage to reproductive functions and to the developing fetus and long term aquatic toxicity has often not been available. Filling such information gaps will allow industry to understand the risks of the chemicals they produce and use, to propose sound risk management measures and to replace them over time with safer alternatives.

To fill the gaps, new studies on chemical substances may have to be conducted, some of them using experimental animals. There are two ways that REACH keeps to a minimum the number of animal tests required.

– Data sharing: REACH encourages that information from tests to establish hazardous properties of chemical substances is shared between registrants as much as possible. Sharing of the results of vertebrate animal tests is mandatory. Such studies should not be repeated.
– Alternative methods and approaches: REACH offers alternatives that can replace some new tests on vertebrate animals, provided that these alternatives are suitable to generate the data required to ensure a high level of protection of human health or the environment. For example, companies can use existing animal studies, conducted before REACH. They can also predict the properties of substances by comparing one substance with another similar one where test data are already available (read-across).

All actors in REACH can play an important part in avoiding unnecessary animal tests. The roles of the following actors are especially important:

– Companies producing or importing chemicals, as REACH registrants, have to gather all available relevant information, share data, and decide on how to generate information seeking to avoid animal testing. If companies consider there are data gaps in the higher tier information requirements for their substance which cannot be filled by non-animal testing approaches, companies make testing proposals for agreement by ECHA.
– Member States who are consulted on all ECHA's draft decisions requesting additional animal tests and are responsible for implementing legislation concerning the protection of animals used for scientific purposes.
– Non-government organizations, scientists or citizens able to make available scientifically relevant information, which can be taken into account when deciding on testing proposals on vertebrate animals for specific substances.

ECHA needs to agree before a new higher-tier study can be conducted. The Agency studies all the testing proposals to check that the proposed test is suitable to generate reliable data for fulfilling the standard information requirement and hereby prevents unnecessary animal testing. Every proposal that involves vertebrate animals is published on the Agency's website and third parties are invited to submit scientifically valid information and studies addressing the substance.

ECHA also facilitates the sharing of available data and information by companies, scientists and citizens. The eChemPortal hosted by ECHA allows ECHA to verify if information on animal tests is already available from other authorities and thereby helps in avoiding unnecessary animal tests.

Finally, ECHA contributes to the development of alternative methods and promotes their use. For example, the Agency develops, in cooperation with the OECD, the QSAR Toolbox, a software application intended to be used by governments, chemical industry and other stakeholders in filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals.

Where animal tests prove essential, REACH requires that the minimum of pain, distress and suffering is caused to the animals. The legislation stipulates that toxicological and ecotoxicological tests have to meet the basic requirements for the care and accommodation of laboratory animals provided in the Directive 2010/63/EU on the protection of animals used for scientific purposes and implementing measures adopted by the Member States in accordance with the directive.

Depending on the hazardous property requiring investigation, the standard tests use in vitro tests (e.g. using bacteria and animal cells) and in vivo tests in animals, such as rats, rabbits and fish, bred specifically for use in experiments. Furthermore, REACH applies the concept of "the three Rs" – replacement, reduction, refinement of animal use. This is a set of of guiding ethical principles which are applied in the alternative methods and approaches stipulated under the REACH Regulation and that help to minimize the harm caused to animals used in science.

ECHA e-News
September 19, 2012

EU: EURL ECVAM launches validation study on methods that identify endocrine disruptors

The European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) intends to carry out a validation study to assess the reliability and predictive capacity of selected methods suitable for identifying chemicals that exhibit androgenic or anti-androgenic activity *in vitro*. The study will focus on methods based on Androgen Receptor Transactivation Assays (ARTA) which typically rely on genetically engineered cell lines that generate luminescence in response to stimulation of androgenic signalling. The ultimate aim of the study is to propose the ARTA test methods to the OECD Test Guidelines Programme for eventual international regulatory acceptance in the form of a Performance Based Test Guideline. Such validated methods will support the implementation of the EU Community Strategy for Endocrine Disrupters[1] and the OECD Conceptual Framework for the Testing and Assessment of Endocrine Disrupting Chemicals[2].

A central element of this study will be a multi-centre ring trial to generate test data on two candidate methods in at least three independent laboratories. The data will be used primarily to assess within and between laboratory reproducibility of the methods and to determine their ability to accurately discriminate between chemicals that instigate or inhibit androgen receptor mediated transactivation *in vitro* and those that do not. The trial will comprise three main phases, namely, the training of participating laboratories on the methods by EURL ECVAM, the transfer of the assays to the participating laboratories, and, finally, the testing of a set of reference chemicals by the participating laboratories using both methods under blind conditions.

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1 http://ec.europa.eu/environment/docum/99706sm.htm

2 http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/oecdconceptualframeworkforthetestingandassessmentofendocrinedisruptingchemicals.htm

GER: New Head of Department of Experimental Toxicology and ZEBET at the BfR

As of October 1, 2012, Prof. Dr Gilbert Schönfelder will head the Experimental Toxicology Department and ZEBET at the Federal Institute for Risk Assessment (BfR). In the Department, toxicologists will closely cooperate with the *National Centre for Documentation and Evaluation of Alternatives to Animal Experiments* (ZEBET), which was established more than two decades ago. ZEBET's objective is to limit the use of animals for scientific purposes to an absolute minimum and to develop alternatives to animal experiments. The BfR has extended this area by means of a joint appointment together with the Charité Universitätsmedizin Berlin. Schönfelder will continue with his work as a full professor at the Charité while at the same time acting as head of the new department and ZEBET at the BfR.

The joint appointment by the BfR and Charité aims at even closer cooperation in the areas of research and at support of young scientists. Thus scientific concepts such as the "3R Principle" for the replacement, reduction and refinement of animal experiments are to be integrated into the fundamental research of the universities to a greater extent in future. Linking the focal points of the tasks within the department with the scientific advice provided by the federal ministries are other important challenges. Schönfelder will represent the BfR in relevant national and international committees.

The Federal Institute for Risk Assessment (BfR) is a scientific institution within the portfolio of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV). It advises the Federal Government and Federal States on questions of food, chemical, and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

Adapted from
ZEBET press release
October 1, 2012

GER: Grants for innovative toxicology for the reduction of animal experiments (e:TOP)

The Federal Ministry for Education and Research (BMBF) aims to support interdisciplinary pilot projects developing alternative methods to animal experimentation by means of molecular biology, omics, bioinformatics, and systems biology. The measure "Innovative Toxicology for the Reduction of Animal Experimentation" is initially announced for pilot projects in order to clarify whether and to what extent a collaboration between these disciplines can contribute to a better understanding of toxicological processes and ultimately to the development of new predictive *in vitro* test methods to replace animals experiments. These projects will serve as a scientific basis for the subsequent translation phase.

Funding is available for innovative, application-oriented pilot projects of interdisciplinary research collaborations that aim to generate substantial scientific progress in the understanding of toxicological processes in the human body. Using established methods, researchers are to investigate in parallel the effects of chemical substances (as defined in the European Chemicals Regulation REACH) on the transcriptome, the relevant proteome, the metabolome, and, if mutagenicity is possible, also on the genome. The metabolism should be one of the priorities in the functional analysis of integrated data. Human cell lines or *in vitro* models of human tissue should be used. Molecular effects of toxicity should be studied and used as a basis for the selective developments of future toxicity tests that can replace animal testing. To this end, the systems biology approach is to be applied, consisting of an iterative cycle of biological experiments and predictive mathematical modelling. Selecting suitable parameters for the toxicological experiments will enable researchers to validate their findings, using existing reference data, if applicable.

Applications may be filed by universitites, non-academic research instiutions, and commercial undertakings headquartered in Germany. The participations of small and medium-sized enterprises is explicitly encouraged.

Funding may be granted for a period of up to 24 months. The application process has two stages:

- January 31, 2013: portal for submission of project outlines closes
- Tba: submission of formal funding application

A partnering day for presentation of project ideas and discussion with potential partners take place in Berlin on November 12, 2012.

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http://www.bmbf.de/foerderungen/19812.php

Adapted from eTOP english version.pdf
Posted on http://AltTox.org by Horst Spielmann
September 10, 2012

GER: Hessian animal welfare prize awarded

This year, the Hessian animal welfare research prize of € 15,000 euros was awarded jointly to *Dr Sascha Meyer dos Santos* from the Institute of Clinical Pharmacology of the University of Frankfurt and to *Andreas Daus* of the Technical University of Darmstadt. In addition, the team of *Prof. Wolfgang Kleinekofort* and *Prof. Friedemann Völklein* was honored for their achievements in the development of an animal replacement technique.

Dr Meyer dos Santos developed a method to investigate how thrombocytes stick to injured blood vessels. Instead of using genetically modified mice, he developed a flow chamber system using human blood vessels from bypass operations.

Dr Daus developed a biosensor on the basis of 3D cell culture systems to test pharmacologically active substances or non-ionizing radiation. A novel rotation mechanism stimulated heart and nerve cells to form spheroids. Action potentials could be measured by microelectrodes.

Prof. Kleinekofort and Prof. Friedemann Völklein established a procedure to measure heat production of cellular structures on the surface of implants with high sensitivity. This shall enable testing of implants with regard to their effects on cellular vitality, toxicity, and rejection reactions in lieu of animal experiments.

Adapted from
Menschen für Tierrechte
press release
September 11, 2012

GER: No animal experiments for US military training

The US company Deployment Medicine International, which was planning to perform experiments on live pigs on behalf of the US army, withdrew a lawsuit against the German Federal State of Thuringia on October 2. The experiments were to be performed to train soldiers and paramedics. The initial application to perform the experiments to the Social Ministry of Thuringia had been denied in 2010 after which the lawsuit was filed. The planned experiments involved subjecting anaesthetized pigs to battlefield injuries such as stab wounds and limb amputations for which a variety of realistic dummies are available. After three independent experts had judged the experiments to be unscientific and of limited educational value the company withdrew the law suit.

The German army no longer performs animal experiments for training purposes and it is currently discussed in the US to ban animal experiments for military purposes.

Adapted from
Menschen für Tierrechte
press release
October 2, 2012

GER: Alternative methods for acute lung injury and acute respiratory distress syndrome research available

In the database for alternative methods to animal experiments (AnimAlt ZEBET), two new documents portraying alternative animal-free fundamental research methods on acute lung injury and acute respiratory distress syndrome are available.

What was presented was a biomimetic, *"breathing" lung on a chip* and a model that makes use of *perfused donor lungs*. The experiments currently conducted in this type of research involving rodents, dogs and other animals are very hard on the animals, making it all the more important to find alternative approaches here. The two techniques presented use human primary cells and/or human tissue and are thus preferable to animal models even from a translational viewpoint (transfer to clinical application).

AnimAlt-ZEBET is a high-quality database of alternative methods to animal experiments in English which is compiled by the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET) at the Federal Institute for Risk Assessment. It can be accessed free of charge at the Internet address: http://www.dimdi.de/static/en/db/dbinfo/zt00.htm

ZEBET News
September 26, 2012

IRAN: Alternatives outreach in Iran

InterNICHE Co-ordinator Nick Jukes visited Iran in April and June 2012 as an invited international speaker at the 17th Iranian Veterinary Congress and to conduct outreach to universities. A previous InterNICHE visit to Iran in 2011 had been the first alternatives outreach to the country. The 2012 outreach was part of a wider project that included extended stays in Uzbekistan and Kyrgyzstan.

The presentation on humane education and alternatives at the Congress in Tehran was complemented by a stall organized by InterNICHE Partners the Iranian Anti-Vivisection Association (IAVA). A range of alternatives including software, models, mannekins and simulators were presented. The positive feedback and opportunities to network with veterinary teachers and students made a very successful event. Discussions were also held to explore with veterinary students the possibility of co-organizing a student-focused alternatives conference as a satellite to a larger veterinary congress in the future. Opportunities for further outreach and meetings were identified. A meeting with zoologists at the Marine Sciences University was held, and talks to over 100 people were given at two branches of the Islamic Azad University – the Faculty of Veterinary Medicine in Garmsar and the Science and Research Branch in Shahriar – organized by IAVA Director Dr Ramak Roshanaie.

In the (all-male) Garmsar branch, and in Shahriar, veterinarian Dr Shahabeddin Safi presented the case for alternatives in research and testing, and Nick Jukes explored the range and quality of alternatives in education and training. Demonstrations of innovative learning tools within anatomy, physiology, pharmacology, clinical skills, and surgery were given. For many teachers and students this was their first significant exposure to alternatives, and the first time that animal experiments had been com-

prehensively challenged. Student interest was very high, reflecting widespread discomfort with harmful animal use, and many teachers recognized the pedagogical, ethical and economic advantages of alternatives.

A subsequent important meeting with the Dean of the Veterinary Faculty at Tehran University was also very positive, with the Dean acknowledging the positive role that alternatives can play within education, and placing their gradual implementation within the process of reform. Iranian campaigners saw this as a very positive response. A seminar at the Faculty just for heads of department and other officials will now be proposed.

A number of students offered to help with promotion of alternatives, and a team of student translators was established to help translate the new InterNICHE website into Farsi. A meeting with students from different universities was held to establish a student alternatives group, and a number of meetings with IAVA campaigners were also held to strategize and build community. Such meetings are very important, particularly with Iranian censorship and international sanctions isolating the country and its people from many international connections.

In September 2012 IAVA was given the Brown Bear Award by Iran Animal Rights Watch for being the most active animal rights group in Iran. The ability of IAVA and its associated fledgling vegan movement to campaign in Iran reflects both the motivation of its members and the degree to which animals are considered by some others to be particularly unworthy of consideration. Campaigners, however, are often aware of the multiple positive impacts – in terms of pedagogics, ethics and empowerment – of organizing for change and establishing humane education.

The contrast with seemingly more moderate countries such as Egypt is also interesting. While Egypt has a well-established and widespread animal welfare movement, only some campaigners are vegetarian, and few are vegan. While such dietary practices are not necessary for alternatives campaigning, they can reflect greater awareness and compassion, and suggest a commitment to ethical consistency. The movement for animals in Iran is younger and very much smaller, but is more animal rights, antivivisection and vegan oriented. By the second half of the 20th century, Iran had developed a sizeable liberal and educated middle class, and the critical thinking and confidence that education can provide has carried through to the present day, particularly in Tehran. Egypt, by contrast, has a more agricultural base and does not have the same level of education – though during the recent revolution there was a call by some students for the implementation of replacement alternatives in education as part of a broader challenge to convention and corruption – see: http://www.altex.ch/resources/387393_Elzaabalawy3.pdf

The conditions and treatment of animals in both countries are perhaps similar. Beating to death of dogs in public is not unknown in Iran, and in Egypt the killing of animals by lacing food with poison or glass shards is also done. Iranian campaigners noticed immediately with positive surprise that a university student researcher who was helping with a seminar had a companion animal dog in his car and was treating her well.

In terms of animal use in education and training, one student provided testimony of practical labs with rabbits where the animals regained consciousness during experiments, and of horses struggling against untrained students' attempts to insert a nasal tube. IAVA had also identified experiments performed on dogs where their limbs were broken. Other animal experiments and the dissection of purpose killed animals are widespread, but are increasingly being questioned.

Although non-animal learning tools can bring about significant replacement in education and training, in veterinary medicine there is a genuine need for access to animal tissue in some practical classes. The default position for some universities, however, is for animals to be killed to provide their cadavers, and it is wrongly assumed that the choice is between killing animals for this purpose or not using animals at all. However, the provision of ethically sourced animal cadavers through Body Donation Programs provides a creative, ethical solution that is increasingly being explored by universities.

The InterNICHE Policy, which IAVA follows, includes ethically sourced cadavers as an alternative because they can replace the use of purpose-killed animals. Ethically sourced animal cadavers are defined by the Policy as those that come from free living animals that have died naturally, in accidents, or that have been euthanised for medical reasons. See http://www.interniche.org/en/about/policy for the full InterNICHE Policy.

Nevertheless, IAVA will source cadavers only from those animals who died naturally or in accidents (many dogs are indeed killed on the streets in traffic accidents), and will reject those that have been euthanized in Iran. They consider that some "euthanasia" in the country is not genuine euthanasia, i.e., mercy killing performed for the animal's benefit due to serious non-recoverable injury or disease, but instead comprises killing for convenience, reflecting poor veterinary principles and practice.

The decision to establish a formal Body Donation Program in Iran was made after the 2011 InterNICHE outreach. IAVA campaigners who are veterinarians are working to establish the infrastructure for such a program, and have already begun promoting the concept to build a network of participating veterinary clinics. To be successful, such programs need good public promotion. Through this, clients will understand that donating the body of their beloved deceased companion animal will directly save the life of another animal, and that their participation will help ensure ethical and effective training for a new generation of humane vets. Feedback from clinics and animal guardians in Iran suggests that there is indeed public support for such a program. Consent forms and good record keeping will ensure that the InterNICHE Policy and other elements of best practice are followed. At the other end of the chain, good working relationships with teachers and faculties willing to use donor animals are being established, along with appropriate infrastructure such as an effective notification process, transportation solutions and cool rooms and freezer storage – funds permitting.

Such programs link an existing resource (cadavers scheduled for incineration) with an existing need (cadaver

requirements for anatomy, pathology, clinical skills and surgery labs), thereby obviating the killing of animals for their cadavers. Replacement is therefore achieved. This alternative approach holds great potential not only in terms of saving lives, but also from the economic and environmental perspectives.

It is recommended that shelters and clinics contribute to the establishment of a Body Donation Program in conjunction with IAVA and InterNICHE, to help stop the catching and killing of dogs for practical classes in veterinary education and training. Dr Parisa Kiani Amin, through the Proshat Pet Clinic in Tehran, is willing to help establish and contribute to this Body Donation Program, and is also able to offer reduced price treatment to shelters. The possibility of the clinic providing a base for training alternatives is being explored.

Already there is a mini-library of alternatives in Iran, with learning tools provided by InterNICHE, and the advanced clinical skills training mannekin Critical Care Jerry is now available for long-term use in the country. In terms of promoting alternatives, Jerry provides a very visual, hands-on tool for use in outreach at exhibitions, conferences and meetings. Functionality includes opportunities to practice intubation, injections and taking blood, and fixing broken bones, without the stress, injury and death caused to animals in practical classes. The breath and heart sounds simulator is an excellent tool that provides opportunities to listen to and become familiar with the sounds of over 20 pathologies. The mannekin can therefore not only bring about replacement of harmful animal use, but through the simulator concentrates many years of clinical experience into one learning tool. He can be of great value to universities as well as to shelters. In South Africa the NSPCA are using him not only to train vets and later to bring about replacement, but also to teach correct ways to approach and handle animals, and provide primary animal care, in the townships.

Other positive changes in Iran have included the release of frogs destined for a practical class into a forest; the ending of seizure tests in pharmacy education at Shahid Beheshti University; and the ending of experiments on dogs and rabbits by a head of physiology. The same teacher borrowed the Biopac Student Lab from the InterNICHE Alternatives Loan System and was very impressed with its potential as a self-experimentation apparatus and replacement for the last remaining animal experiments in his class. And several universities are now interested in using Critical Care Jerry as a training tool.

For many alternatives, the sanctions were identified as a barrier to their import and subsequent implementation. Local production of alternatives was recognized as one solution. Another area of interest from teachers was reflected in requests that InterNICHE and IAVA should organize a workshop on plastination. This method of dehydrating tissue and using silicone and other materials to preserve specimens can produce durable models that are alternatives to dissection. Working with this specific interest from the teachers will also provide an opportunity to open the door to the broader field of alternatives.

InterNICHE gratefully acknowledges funding support from Doctors Against Animal Experiments (DAAE) (Germany) for the activity in Uzbekistan and Kyrgyzstan; and from the Anti-Vivisection Union (South Australia) (AVU), the International Association Against Painful Experiments on Animals (IAAPEA), Animalearn and Mrs Sheelagh Graham for the whole project. The assistance of Ms Sepideh Hosseini is also acknowledged. A report on Uzbekistan and Kyrgyzstan is to follow.

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PERU: Peruvian humane education outreach tour

In the last two weeks of August I visited Peru for an outreach tour organized by the Peruvian organisation *Unidos por los Animales* (UPA; http://www.unidosporlosanimales.org/). I had the opportunity to deliver 20 main powerpoint presentations on humane teaching methods within veterinary and other biomedical education, animal experiments and alternatives, animal welfare standards within the veterinary profession, and several other animal protection topics (presentations are at http://www.andrewknight.info/presentations/presentations.html). Additionally, academics from several veterinary schools in Lima delivered presentations on the successful use of humane teaching methods within their disciplines (e.g., anatomy, physiology, surgical and clinical skills training) and universities. These were mostly delivered at four humane education and animal welfare conferences organized by UPA in Lima and two other cities. Audiences varied from around 50-150 and were mostly comprised of students, faculty members and animal advocates. Several additional presentations were provided during meetings at universities, as well as one presentation at a Small Animal Veterinary Association meeting in Lima.

Eight successful meetings were held at universities (mostly veterinary schools, with some other faculties), or with faculty members. Deans of veterinary schools were present (twice), and even a University Vice-President (once), along with senior surgical instructors, or faculty members in charge of key animal-using disciplines, such as physiology. UPA did extremely well to secure these meetings. Four main exhibitions of humane teaching methods supplied from the InterNICHE international and Peruvian alternatives libraries were held, with some mannequins also supplied by a veterinary

school in Lima. These were made by students or faculty. There was considerable media coverage.

Audiences were generally very receptive to our information and messages. It was exciting to see large numbers of veterinary and other students so interested in our exhibitions of alternatives, along with television and radio stations and their reporters, and, perhaps most importantly, the academics in charge of courses. It was inspiring to see their enthusiasm for humane teaching methods, and to learn of their own initiatives, sometimes assisted by the work of APEH in Peru. For example, the anatomy museum at the Veterinary Medicine School of the *Universidad Nacional Mayor de San Marcos* in Lima included a large collection of "ethically-sourced cadavers" (skeletons or bodies obtained from animals that have been euthanized for medical reasons, or that have died naturally or in accidents). Similarly, to overcome the prohibitive costs of acquiring additional venipuncture (blood draw) mannequins from the US, students and faculty at the *Universidad Ricardo Palma* veterinary school in Lima have mastered the art of cheaply making their own. They now have an impressive range of these mannequins which we enjoyed exhibiting, to help encourage other universities to similarly overcome their financial limitations.

Perhaps most exciting of all, however, were our communications with very senior faculty at a veterinary and a medical school in Tacna. Both had been the subject of recent media controversy and campaigns following publicity of their harmful use of animals, particularly, use of stray dogs in terminal surgical laboratories. Following our meeting with the medical school faculty, they accepted their students could gain similar surgical experience by assisting veterinarians sterilizing these street dogs, as part of a charitable neutering program. I very much hope that this will proceed, and be successful. And it was amazing to see faculty from the veterinary school address the audience of around 100 at the end of our humane education and animal welfare conference there, to tell everyone that their eyes had been opened, and that they would seriously consider introducing humane teaching methods!

I'm grateful to the Swiss organization *Aktionsgemeinschaft Schweizer Tierversuchsgegner* (http://www.agstg.ch/) for sponsoring my trip to Peru, and to InterNICHE (http://www.interniche.org/) for supplying the humane teaching alternatives exhibited.

Andrew Knight
DipECAWBM (WSEL), PhD, MRCVS, FOCAE
http://www.AnimalConsultants.org

SUI: 3R Research Foundation calls for grant applications

The 3R Research Foundation Switzerland invites interested scientists to propose a project to reduce the impact on animals used in animal experimentation and/or reduce the number of animals needed for a specific research topic (animal model) and/or to replace specific experiments using animals. The duration of the project proposed should preferably be between 1 and 3 years and the budget required should be between CHF 50,000 and CHF 250,000.

Applications from researchers working outside Switzerland will be considered only in exceptional cases. They must show that they have links with an institution in Switzerland or with a researcher in Switzerland.

In 2013 a total of around CHF 500,000 (€ 400,000) will be available for new projects.

The application procedure comprises 2 stages:

- February 1, 2013: Deadline for submitting project outlines
- July 1, 2013: Deadline for submitting full applications

More information:
http://www.forschung3r.ch/en/guidelines/index.html

Adapted from
http://www.forschung3r.ch

UK: Call for 3Rs Prize applications

The NC3Rs awards an 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. The prize is part of the Centre's commitment to recognize and reward high quality research which has an impact on the use of animals in the life sciences.

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.

The 3Rs prize is for a piece of primary research published in a peer-reviewed journal in the last three years and is open to any researcher, in academia or industry. The prize is awarded to the principal investigator, research team leader, or other nominated author. The prize is now open to international groups. For further details on eligibility, see: http://www.nc3rs.org.uk/page.asp?id=150

The deadline for entries is 4 p.m. on December 13, 2012.

For further information on the 3Rs Prize, please contact: 3Rsprize@nc3rs.org.uk

Adapted from
NC3Rs e-newsletter 47
September 21, 2012

USA: US Consumer Product Safety Commission (CPSC) publishes Guidelines for Animal Testing

The U.S. Consumer Product Safety Commission (CPSC) has added a page to its website entitled "Recommended Procedures Regarding the CPSC's Policy on Animal Testing" (http://www.cpsc.gov/library/animaltesting.html).

The page summarizes the CPSC policy on animal testing and emphasizes the CPSC's support for the use of existing information and scientifically validated alternatives to animal testing in hazard assessment. The page also lists acceptable alternative methods for acute toxicity testing, ocular irritation testing, dermal irritation testing, and skin sensitization testing, and provides links to CPSC votes or approvals with respect to animal testing policy.

CPSC is a member agency of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), which is administered and supported by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Links to the CPSC website and the new CPSC alternatives page are available on the NICEATM-ICCVAM website. Links to websites of the other 14 ICCVAM member agencies are also available on this page, as are links to pages on these websites specifically discussing animal testing and alternatives use.

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October 6, 2012

USA: EPA grants to advance chemical safety research

On September 13, 2012 the U.S. Environmental Protection Agency (EPA) announced nearly $ 11 million in grants to eight universities through EPA's Science to Achieve Results (STAR) program. These grants will help the universities develop fast and effective methods to test chemicals' toxicity to people and the environment. These innovative testing methods will be used to predict a chemical's potential to interact with biological processes that could lead to reproductive and developmental problems, and disruption of the endocrine system.

The grantees will focus on developing methods and models to predict how exposure to environmental and synthetic (manmade) chemicals and chemical mixtures may harm the public. Some synthetic chemicals are known endocrine disruptors, which interfere with or even mimic natural hormones and cause damage to the development and function of vital organs, particularly in young children and developing fetuses. There are currently thousands of chemicals in use and hundreds more introduced every year.

More information on the grant awards: http://www.epa.gov/ncer/hi_thruput_assays

U.S. Environmental
Protection Agency
Weekly Digest Bulletin
September 13, 2012

USA: ALTBIB portal updated

The National Library of Medicine (NLM) ALTBIB portal has been updated. ALTBIB provides access to PubMed®/MEDLINE® citations relevant to alternatives to the use of live vertebrates in biomedical research and testing. ALTBIB is located at: http://toxnet.nlm.nih.gov/altbib.html

The site's topics and subtopics are aligned with current approaches. For example, information is provided on *in silico*, *in vitro*, and improved (refined) animal testing methods. Strategies which incorporate validated methods and other approaches are also covered.

In addition to the topic area PubMed searches, the ALTBIB portal includes a searchable bibliographic collection on alternatives to animal testing. This collection provides citations from published articles, books, book chapters, and technical reports published from 1980 to 2000. The bibliography features citations concerning methods, tests, assays, and procedures that may prove useful in establishing alternatives to the use of intact vertebrates.

ALTBIB has an extensive collection of links to key organizations providing information on alternatives to animal testing, and provides access to animal alternatives news sources, such as the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), of which NLM is a member. The portal also offers access to ICCVAM's "International Acceptance of Alternative Methods, 1998-2012" and "U.S. and International Milestones in Alternative Test Method Development and Evaluations."

A fact sheet with more information about the ALTBIB portal is available on the NLM website: http://www.nlm.nih.gov/pubs/factsheets/altbibfs.html

Catherine Sprankle
Posted on AltTox.org
September 25, 2012

USA: Funding opportunity for developmental neurotoxicity research

The U.S. Environmental Protection Agency (EPA), as part of its Science to Achieve Results (STAR) program, is seeking applications proposing research that will identify and/or provide a better understanding of adverse outcome pathways (AOPs) that lead to developmental neurotoxicity (DNT). Such research should advance the state of knowledge by linking key events along the continuum from exposure to adverse outcomes, including windows of susceptibility, and ultimately resulting in AOP-based data and models for chemical testing that will allow risk assessors to predict DNT. EPA is particularly interested in funding research projects that focus on endocrine signaling pathways that alter neurodevelopment, but will accept research proposals that address other AOPs.

Public nonprofit institutions/organizations (includes public institutions of higher education and hospitals) and private nonprofit institutions/organizations (includes private institutions of higher education and hospitals) located in the U.S., state and local governments, Federally Recognized Indian Tribal Governments, and U.S. territories or possessions are eligible to apply.

"Development and Use of Adverse Outcome Pathways that Predict Adverse Developmental Neurotoxicity" EPA-G2012-STAR-F1

- Anticipated Type of Award: Grant or cooperative agreement.
- Estimated Number of Awards: Approximately five awards.
- Anticipated Funding Amount: Approximately $ 4 million total for all awards.
- Potential Funding per Award: Up to a total of $ 800,000 including direct and indirect costs, with a maximum duration of four years. Cost-sharing is not required. Proposals with budgets exceeding the total award limits will not be considered.
- Solicitation Closing Date: December 12, 2012

For information:
http://epa.gov/ncer/rfa/2012/2012_star_neurotox.html

USA: FDA issues guidance on alternative pyrogen tests

The U.S. Food and Drug Administration (FDA) has issued guidance on the use of alternatives to the rabbit pyrogen test (RPT) and the bacterial endotoxins test (BET) for detecting pyrogens in pharmaceuticals and other products. "Guidance for Industry – Pyrogen and Endotoxins Testing: Questions and Answers," issued June 2012, includes guidance regarding the use of alternatives to the RPT or the BET. Firms producing products for which pyrogen testing is required may use alternative methods if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, and in other special circumstances. Alternative methods should be subjected to appropriate validation and shown to achieve equivalent or better results compared to the standard method. The document also provides guidance for transitioning from one test method to another.

As examples of alternative assays that may be used, the guidance document cites the recombinant horseshoe crab Factor C assay and monocyte activation type pyrogen tests (MATs). ICCVAM recommended in 2008 that MATs could be considered for use to detect Gram-negative endotoxin in human parenteral drugs on a case-by-case basis, subject to validation for each specific product to demonstrate equivalence to the RPT, in accordance with applicable U.S. Federal regulations. The ICCVAM recommendations were accepted by Federal agencies, including the FDA. Information on the NICEATM-ICCVAM evaluation of the *in vitro* pyrogen test methods can be found on the NICEATM-ICCVAM website at: http://iccvam.niehs.nih.gov/methods/pyrogen/pyrogen.htm

ICCVAM has given a high priority for further discussion to a 2011 nomination to ICCVAM for activities to expand the applicability domain of a MAT that measures IL-1 release from cryopreserved human blood cells to include detection of non-endotoxin pyrogens.

The FDA guidance is available on the agency's website at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM310098.pdf

Catherine Sprankle
Integrated Laboratory Systems, Inc./Contractor supporting the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods National Institute of Environmental Health Sciences Research Triangle Park, NC 27709

USA: PETA seeks Scientific Advisor

People for the Ethical Treatment of Animals seeks a Scientific Advisory to provide research support for a wide range of animal-testing issues in furtherance of PETA's advocacy on behalf of animals used in government-mandated testing.

Primary Responsibilities and Duties:
- Research and interpret a variety of animal-protection issues, primarily relating to animal testing required by regulatory agencies
- Identify, review, and develop recommendations for non-animal test methods through analysis of scientific literature and data sources
- Secure and lead formal meetings with government agencies for scientific discussion of toxicity-testing concerns
- Attend scientific conferences and communicate with scientists on specific issues relating to animal and non-animal test methods
- Obtain the necessary data for writing factsheets, white papers, reports, Federal Register comments, Organization for Economic Co-operation and Development submissions, correspondence, and other documentation
- Analyze technical papers and translate scientific terminology into lay terms for use in research projects
- Present complex and potentially controversial organizational recommendations and routinely represent the organization in dealings with state and federal agencies, public- and private-sector organizations, international forums, multinational companies, media, and advocacy and special-interest groups
- Participate in strategic planning for the Regulatory Testing Division
- Perform any other duties assigned by the supervisor

Requirements:
- Advanced degree in a related field and three years of relevant experience
- Proven extensive knowledge of animal-testing issues and medical and scientific terminology
- Familiarity with federal and international regulatory agencies
- Proven ability to interact effectively with diverse groups of scientists and media representatives
- Demonstrated ability to analyze and interpret complex technical documents
- Demonstrated exceptional public-speaking skills
- Demonstrated exceptional writing and research skills
- Proven ability to maintain strict confidentiality at all times
- Proven ability to work well under pressure and within tight deadlines
- Ability and willingness to travel
- Must be at least 21 years of age and have a valid U.S. driver's license, a minimum of three years of driving experience, and a satisfactory driving record
- Support for PETA's philosophy and the ability to professionally advocate PETA's positions
- Commitment to the objectives of the organization

Please apply online:
https://www.appone.com/MainInfoReq.asp?R_ID=575537

Scientific Advisor – Full time
Position is open & available now, no closing date
Contact: jobopenings@petaf.org
The position is available in several cities in the States. Washington, DC; Oakland, CA; Los Angeles, CA or Norfolk, VA. Applicant must be a U.S. citizen, lawful permanent resident or an alien authorized to work in the United States.

Natalie Hawkins
PETA Foundation