



News

BRA: Brazilian Center for Validation of Alternative Methods established

The Brazilian Center for Validation of Alternative Methods (BraCVAM) was established on September 17, 2011. During the celebration of the 30th anniversary of the National Institute of Quality Control in Health (INCQS) a cooperation between Oswaldo Cruz Foundation (FIOCRUZ) and the National Agency of Health Surveillance (ANVISA) was established for the creation of BraCVAM.

As soon as BraCVAM was created, the Ministry of Science, Technology and Innovation (MCTI) established the Alternative Methods National Network which will be coordinated by BraCVAM and IN-

METRO (National Institute of Metrology, Normalization and Industrial Quality).

These efforts aim to join together Brazilian groups that work on alternative methods on experimentation and education.

When BraCVAM is fully functional it is expected to develop collaborative studies with similar centers around the world.

References

Eskes, C., Sá-Rocha, V. M., Nunes, J., et al. (2009). Proposal for a Brazilian Centre on Alternative Test Methods. *ALTEX* 26, 295-298.

Presgrave, O. A. F. (2008). The need of the establishment of a Brazilian Centre for the Validation of Alternative Methods (BraCVAM). *ATLA* 36, 705-708.

Presgrave, O., Eskes, C., Presgrave, R., et al. (2010). A proposal of establishing a Brazilian Center for Validation of Alternative Methods (BRACVAM). *ALTEX* 27, 27-35.

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EU: Review of REACH in 2012

REACH has been in force for 5 years, and several important milestones in its implementation have already passed. The Commission will launch a review which will consist of the legally required reviews and reports: (a) the review of ECHA (Article 75.2), (b) the review to assess whether or not to amend the scope of REACH in order to avoid overlaps with other EU legislation (Article 138.6), and (c) a general report from the experience acquired in the operation of the regulation (Article 117.4) including a review of the requirements relating to registration of low tonnage substances Article 138(3) and the information submitted by the Member States and ECHA in their respective reports on the operation of REACH (Art.117(1)(2)(3). All these review and reports are to be published by 1 June 2012.

In addition, the review will include a report on the first lessons learnt from the

implementation of REACH with special attention to the costs and administrative burden and other impacts on innovation. All of these reviews and reports will be presented as a package by 1 June 2012, accompanied by a Chapeau Communication to give a complete overview.

To inform the 2012 review process, the Commission will, or has already launched, several thematic studies. They address the following issues which may provide inputs to the Commission services during the review:

- The (nominal) risk caused by chemicals in 2012 compared to the 2007 (a follow-up of the baseline study of REACH)
- Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006
- The REACH contribution to the development, commercialization and uptake of products of emerging technologies

- Implementation and enforcement of restrictions in Member States
- Impact of the REACH regulation on the innovativeness of EU chemical industry
- Inspections requirements for REACH and CLP
- Functioning of the European chemical market after the introduction of REACH regulation
- Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps
- Technical assistance to prepare the Commission report on operation of REACH
- Review of the registration requirements for 1 to 10 tonnes substances and polymers
- Assessment of health and environmental benefits of REACH
- Review of EU legislation (REACH) concerning nanotechnology



As foreseen in article 138 of the Regulation and taking into account the Commission's right of initiative, the Commission may, if appropriate, present a legislative proposal based on the review outcomes and after considering all the expected socio-economic effects through a proper impact assessment process, bearing also in mind, among others, potential impacts on the next registration deadlines (2013 and 2018).

In parallel, the Commission will consider practical approaches to better complement the current legislation e.g. by improving existing guidance documents and/or by preparing new ones, where necessary.

If you want to be kept informed about the launch of consultation processes or surveys, or want to give feedback to any of the above mentioned studies, please send an email to the following address,

stating the study you are interested in:
ENTR-ENV-REACH-REVIEW@
EC.EUROPA.EU

Posted on:
<http://ec.europa.eu>

GER: Berlin Research Prize for Alternatives to Animal Experiments awarded

The first Berlin Research Prize for alternatives to animal experiments was awarded to Dr med. Andreas Hocke from the Medical Clinic of the Charité Berlin. The jury selected his work on the "Establishment and development of a human lung tissue infection model for reducing and replacing animal experiments in mouse pneumonia models" from ten submissions.

Dr Hocke's research aims to replace experiments on mice in lung infection research using human tissue. Instead of using mice, human lung tissue obtained from surgery patients suffering from lung disease is used. Several Berlin hospitals teamed up to provide human lung tissue for research purposes, amongst them the DRK Kliniken in Berlin-Mitte, HELIOS Klinikum Emil von Behring and the Charité Clinic for Thoracic Surgery in Berlin-Mitte.

The model serves the investigation of inflammation reactions caused by severe pneumonia pathogens (e.g., *Streptococcus pneumoniae*, influenza). The project is a central component of the collaborative research project "Congenital Immunity of the Lung", funded by the German Research Foundation.

The Research Prize for Alternatives to Animal Experiments was jointly awarded by the Senate Administration for Health, Environment and Consumer Protection, together with the State Office for Health and Social Affairs (LaGeSo) and the association of the research-based pharmaceutical companies in Germany (vfa). The vfa donated the € 15,000 prize money.

A special prize was awarded to the Lise-Meitner School for the research paper "*Umsetzung eines 3T3 Phototoxizitätstests mit Hypericin unter*

Schulbedingungen zur Ergänzung der Fachpraxis in der Ausbildung zum biologisch-technischen Assistenten" ("Implementation of a 3T3 phototoxicity test with hypericin under training conditions to complete practical experience in the vocational training of biological technical assistants"). The paper was submitted by Jennifer Weigt, Nils Dommershausen, and Florian Butke. The special prize acknowledges the specific adaptation of alternatives to animal experiments for education purposes.

The € 15,000 prize will be awarded annually for outstanding scientific work on the prevention and reduction of experiments on animals.

Posted on:
www.invitrojobs.com



GER: Ethics Prize for Paola Cavalieri and Peter Singer

The Italian philosopher Paola Cavalieri and the Australian philosopher Peter Singer received the Ethics Prize of the Giordano Bruno Foundation on June 3, 2011 in Frankfurt am Main, Germany. The Foundation stands for an “evolutionary humanism” which goes back to the evolutionary biologist and first Director of UNESCO, Sir Julian Huxley. Its motto is “We are not the crowning glory of creation but the Neanderthals of tomorrow”.

The two philosophers received the prize of € 10,000 for their contributions

to improving animal rights. According to the Foundation, the prize especially recognized their fight for basic rights for Great Apes, for which they established the Great Ape Project (GAP). The Great Ape Project demands basic rights, including the right to life, freedom and non-torture for non-human primates. Singer became well known in the debate on animal ethics with his book “Animal Liberation” that was published in 1975 and in which he describes the exploitation of animals and declares it “speciesism”. The book,

published in German in 1980, sparked the contemporary discussion of animal ethics. Paola Cavalieri became well known in Germany with her book “The Animal Question” in 2002. She criticizes the near exclusion of the moral question on the status of animals and demands a minimum level of equality for animals. She advocates an expansion of the theory of human rights to animals.

Petra Mayr
TIERethik

INT: Official approval of OECD TG 443 – extended 1-generation reproductive toxicity study

The International Council on Animal Protection in OECD Programmes (ICAPO, <http://www.icapo.org>) is calling for immediate action by companies and regulatory authorities worldwide to replace the traditional “two-generation” animal test for reproductive toxicity with a new “extended one-generation” method that has just been adopted by the Organisation for Economic Co-operation and Development (OECD, 2011). Although still an animal test, the new one-generation test uses approximately half the number of animals as the old two-generation method (1,400 rats per test vs. 2,600).

The new OECD method was adopted on July 28, 2011, just in time for a large number of reproductive toxicity proposals under the European chemicals regulation “REACH,” the revision of the EU testing requirements for pesticides and biocides, and increased U.S. testing of certain pesticides and industrial chemicals. Within these programs it is esti-

mated that millions of animals could be killed for reproductive toxicity testing alone. The extended one-generation test introduces a number of new parameters designed to better identify “endocrine disrupting” chemicals, and provides for the optional assessment of neurological and immune system parameters when warranted. By assessing all of these parameters in combination rather than as separate studies, animal use can be reduced by up to 70 percent.

Adoption by the 34 member nations of the OECD follows a series of rigorous studies, which found that “the second generation mating and offspring will very rarely provide critical information” (Piersma et al., 2011). In other words, the vast majority of reproductive toxicants are identified in the first generation.

As OECD invited experts, ICAPO provided scientific expertise that helped create the new guideline and ensure its acceptance. In addition, ICAPO member groups are engaged in individual lobby-

ing efforts to ensure regional acceptance of the new protocol across relevant industry sectors.

References

- Piersma, A. H., Rorije, E., and Beekhuizen, M. E. (2011). Combined retrospective analysis of 498 rat multi-generation reproductive toxicity studies: on the impact of parameters related to F1 mating and F2 offspring. *Reprod. Toxicol.* 31, 392-401.
- OECD (2011). Test Guideline 443: Extended one-generation reproductive toxicity study. http://www.oecd-ilibrary.org/environment/test-no-443-extended-one-generation-reproductive-toxicity-study_9789264122550-en;jsessionid=hmrebwtuc4y3.delta

Adapted from <http://forums.alttox.org>
Posted by Kristie Sullivan
August 4, 2011
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INT: “Basel meets Berlin” – transparency is needed for animal experiments

The new EU Directive on animal experiments¹, parts of which were modeled on Swiss legislation in 2010, has to be implemented in all EU Member States by the end of 2012. The signees of the Basel Declaration are calling for uniform rules and the highest standards to be applied in the enactment of this Directive as this is essential for raising public acceptance and understanding for animal research.

Improving the acceptance and understanding for animal research among the general public and politicians was the aim of more than 80 international researchers who gathered in Berlin on October 16-18. This meeting was occasioned by the enactment of the new EU Directive on animal experiments into national law. The scientists formed working groups to develop concrete approaches to improving animal welfare. A further core aspect of the meeting was the demand for transparency, i.e. for comprehensible communication with the general public and politicians. The researchers presented their results to the public in the Swiss embassy, together with representatives of the European Parliament, the European Commission and the Swiss Federal Veterinary Office, and announced the establishment of a new international society.

A year ago, researchers adopted the Basel Declaration, a call for more trust and transparency in animal research. The Declaration has so far been signed by over 800 scientists from all over the world and, like the Declaration of Helsinki², it should serve in the future as a global ethical framework within the field of animal experimentation. October 2011 saw the founding of the international Basel Declaration Society. This society will administer the Declaration and promote its ongoing development (www.basel-declaration.org).

In Berlin, the progress made over the last year and the possibilities of further improving animal welfare and communication were discussed. “A year ago we were asked how a piece of paper was supposed to change practices – today we can show that the Declaration is a living commitment” said Prof. Michael Hengartner from Zurich when he opened the event and presented the first annual report of the Basel Declaration. “We are open to dialogue with everyone who wants to join forces with us on improving animal welfare”, explained Prof. Stefan Treue, Director of Germany’s Primate Center, pointing out that in Berlin animal welfare organizations were invited to the conference discussions for the first time.

Just how difficult it is to address the issue of “animal experiments” politically in Europe was explained by MEP Elisabeth Jeggle (CDU), rapporteur to the European Parliament during the revision of the EU Directive. She urged the governments of the EU Member States to enact the difficult Brussels compromise into national law quickly. Susanna Louhimies, expert from the Environment Directorate-General of the European Commission, called on researchers and animal rights activists to view the new legislation not as a threat but as an opportunity to work together on improving animal welfare.

The individual results of the conference discussions together with more background information on the Basel Declaration Society and its activities can be found at www.basel-declaration.org. For any further questions, discussions with scientists or guided tours of laboratories, please do not hesitate to contact our press office at: presse@basler-konferenz.de

Press release
Basel Declaration Society
Berlin, October 18, 2011

See the Comment
by Franz P. Gruber
on pp. 353 – sva

¹ European Directive 2010/63/EU on the Protection of Animal used for Scientific Purposes – sva

² The Declaration of Helsinki is the successor to the Nuremberg Code, which formulated ethical guidelines for research in humans after the Nuremberg trials of Nazi doctors.



NL: International course in Laboratory Animal Science

A two week intensive course in Laboratory Animal Science will be organized at the Department of Animals in Science & Society, Utrecht University, The Netherlands on July 2-13, 2012. This course has been organized since 1993.

The objective of this course is to present basic facts and principles that are essential for the humane use and care of laboratory animals and for the quality of research. The contents of the course are in line with the recommendations of the

Federation of European Laboratory Animal Science Associations (FELASA) regarding the training of the young scientist whose research involves the use of vertebrate animals.

The course may also be of interest for those who intend to set up a similar course in their own country. For this purpose, during the course the acquisition of teaching materials can be discussed with the course committee.

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UK: Dr Hadwen Trust announces funding opportunity

The Dr Hadwen Trust invites applications from UK-based researchers for research which will advance scientific and medical knowledge and replace the use of laboratory animals in medical research. Grants are not available simply in support of non-animal research per se. The research must be directed towards replacing the use of living animals in current procedures within the applicant's laboratory or, preferably, in the wider field.

Research which requires or involves the use of living animals in any way, even though the ultimate aim may be to replace their use, will not be supported. The purchase or maintenance of animals will not be funded for any reason.

Proposals relevant to any area of medical research or testing can be considered and applications that integrate a range of

disciplines are welcomed. Applicants are encouraged to outline the potential benefits of the proposed work in both scientific and replacement terms. It is important to provide measures of impact, e.g., an estimate of the number of animals replaced or what scientific advantages it could have over other *in vivo/vitro* methods. Assessment will take account of the applicants' strategy for promoting the proposed research to their scientific peers, for example through publications and presentations at scientific conferences. The Dr Hadwen Trust does not award Full Economic Costs (FEC).

A grant may be awarded for any period of up to 3 years. The financial support requested should be tailored to the scientific needs of the proposal. The maximum amount of funds that can be requested is £

60,000 per year of which a maximum of £10,000 can be for consumables. Requests for funding can include the salary of the position applied for, consumables, equipment and other costs (if applicable).

Applications run in 2 stages. The deadline for returning a preliminary application form is Wednesday, December 21, 2011 at 5 pm. If selected, applicants will need to complete a full application form. Forms are available at:
www.drhadwentrust.org/Grants

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UK: InterNICHE honored for replacement of animal experiments in RSPCA Award

The RSPCA has conferred upon Nick Jukes of InterNICHE the prestigious Lord Erskine Silver Award.

At the RSPCA Honors ceremony in Horsham (UK) on September 3, Chair of the RSPCA Council Michael Tomlinson and actor Brian Blessed presented

the Award in recognition of an outstanding contribution to the field of animal welfare.

Mr Tomlinson acknowledged the tireless efforts of Nick and of InterNICHE as a whole in the field of humane education and alternatives to animal ex-

periments. He described how a network based almost entirely on voluntary input had been built up to a global level by harnessing the enthusiasm of local contacts. InterNICHE outreach has often provided the first significant exposure to alternatives in some countries, and widespread



replacement has been achieved by working with teachers and students.

Nick Jukes said: "My work involves helping to realize the vision of a fully humane education in medicine, veterinary medicine and biological science. InterNICHE campaigns internationally to replace dissections and animal experiments with innovative alternatives whose pedagogical, ethical and economic advantages benefit students, the professions, and animals. Winning this Award means a great deal. It is a valu-

able recognition of the many successes achieved in replacing harmful animal use in education and training across the world. It acknowledges the impressive commitment of and huge voluntary effort by the whole InterNICHE team, and reflects the growing momentum for the implementation of humane alternatives."

The Award was established in memory of Lord Erskine, who successfully steered Richard Martin's Bill "to prevent the cruel and improper treatment of

cattle" through the House of Lords. The Bill became law in 1822 and formed the foundation for subsequent statutes for the prevention of cruelty to animals.

Other recipients of the 2011 RSPCA Honors include Jill Robinson from Animals Asia, Wu Hung from EAST in Taiwan, and journalist Danny Penman.

Press release
InterNICHE
September 5, 2011

UK: ECEAE seeks toxicologist

The REACH testing proposal 45 day scrutiny period is a facility built into new EU chemicals legislation REACH to prevent animal testing by enabling third parties to submit information on the chemical substance or other additional scientific information.

The ECEAE is Europe's leading alliance of animal protection groups peacefully campaigning on behalf of animals in laboratories. We have been serving the testing proposals system since its start in 2009 and are looking to expand our activity in line with the volume of proposals now being published by the European Chemicals Agency (ECHA).

We are looking for expressions interest for toxicology or regulatory specialists to help us with this.

Job description: Examination of testing proposals on a routine basis in order to determine whether the data required already exists or can be obtained by other (animal-free) testing methods and submission of technical comments on this within 45 days.

Prerequisites:

- Experience in toxicology and regulatory submissions, ideally for chemical substances.
- Experience in researching for information on substances and animal-free

testing methods.

- Excellent (professional) written and spoken English.
- Dedication to animal welfare.

Salary: Full-time or part-time employment or payment on a project basis are possible. Voluntary collaboration is also welcome.

Please send a short application with curriculum vitae and salary or fee expectation to reach@eceae.org

Telephone enquiries to Dr Katy Taylor +44 20 7619 6979

Posted on:
<http://eceae.org/>

UK: NC3Rs kick off CRACK-IT Challenges competition

The CRACK-IT Challenges competition was launched in London on September 20, 2011. This competition poses specific challenges to the scientific community to develop new technologies or methods that could greatly reduce the use of animals for scientific purposes or improve their welfare. It is run as a collaboration between the NC3Rs and the Technology Strategy Board through their Small Business Research Initiative.

The Challenges are co-sponsored by the NC3Rs and industry. They call on academic and/or SME applicants to submit applications for financial support and in-kind contributions from individual companies. The submission deadline for the six Challenges was on November 2, 2011, but the website www.crackit.org.uk now calls on the scientific community for submission of further challenges in this field. These are not associated with

financial support from the NC3Rs but aim to team up challengers with potential solution providers.

The CRACK-IT newsletter provides information on the program: <http://www.nc3rs.org.uk/submit-crackit.asp>

sva



USA: CAAT to pioneer transformative research in toxicology testing

The Johns Hopkins Center for Alternatives to Animal Testing (CAAT) has received a \$ 6 million grant from the National Institutes of Health (NIH) to pioneer potentially revolutionary new methods for toxicological testing to improve human health and reduce animal testing.

CAAT Director Thomas Hartung, MD, PhD, and his team at the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland, along with partner Agilent Technologies and noted scientists from government and industry, received the funding for a consortium to develop a new technological methodology for mapping the molecular pathways of toxicity within cells. Funding for the project comes from the Common Fund's NIH Director's Transformative Research Projects Program (R01), which is designed to support exceptionally innovative, high risk, original and/or unconventional research that has the potential to create or overturn fundamental scientific paradigms.

Current toxicological testing relies on a patchwork of 40+-year-old animal tests that are expensive (more than \$ 3 billion per year), time-consuming, and often provide results of limited predictive value for human health. The low-throughput of current toxicity testing approaches (which are largely the same for industrial

chemicals, pesticides, and drugs) has led to a backlog of more than 80,000 chemicals for which potential toxicity remains largely unknown.

Scientific understanding of how genes, proteins, and small molecules interact to form molecular pathways that maintain cell function has evolved rapidly, thanks to advances in molecular and computational tools. Pathways that lead to adverse health effects when perturbed are referred to as pathways of toxicity (PoT). "Mapping the entirety of these pathways – which I've termed the 'Human Toxome' – will be a large-scale effort, perhaps on the order of the Human Genome Project," Hartung says. A proposal to map the Human Toxome was first published in *ALTEX* (Hartung and McBride, 2011).

As a first step to mapping the Human Toxome, Hartung and his collaborators have proposed comprehensively mapping the pathways of endocrine disruption, a perturbation of the hormonal system that can cause tumors, birth defects, and developmental disorders. The physiological pathways of the endocrine system are relatively well understood, making PoT identification simpler than for other potential targets. The team will develop a common, community-accessible framework that will enable the toxicology community at large to comprehensively and

cooperatively map the human toxome using integrated testing strategies that combine "omics" (transcriptomics and metabolomics) data with computational models. The consortium will also create a public database of PoT, enabling full access to researchers around the world.

Along with Hartung, the other principal investigators include James Yager, Bloomberg School of Public Health; Robert Kavlock, Director of the National Center for Computational Toxicology at the U.S. Environmental Protection Agency (EPA); Michael Rosenberg, Director of Genomics Software Life Science Group at leading systems biology technology provider Agilent Technologies; Mel Andersen, Associate Director of the Hamner Institute for Health Sciences; Kim Boekelheide, Professor of Medical Sciences at Brown University; and Albert J. Fornace, Jr., Molecular Cancer Research Chair at Lombardi Comprehensive Cancer Center, Georgetown University Medical Center.

Reference

Hartung, T. and McBride, M. (2011). Food for thought ... on mapping the human toxome. *ALTEX* 28, 83-93.

Adapted from CAAT Press release
September 20, 2011
<http://caat.jhsph.edu>