



News

EU: ECHA decision on rabbit inhalation studies annulled

The Board of Appeal on April 29, 2013 annulled an ECHA decision requiring a 90-day repeated dose toxicity study in rabbits. ECHA had requested an inhalation study in rabbits for the coolant 2,3,3,3-tetrafluoropropene following a dossier compliance check. The substance in question had caused the death of pregnant rabbits in a prenatal developmental toxicity study.

The Board of Appeal found that although more information on the substance in question was necessary, ECHA had

not assumed the responsibility “to ensure that testing on vertebrate animals is only undertaken as a last resort” and “failed to ensure a test using the minimum number of vertebrate animals would be used.” Further, the Board of Appeal concluded that in the present case ECHA’s decision “breache[d] the principle of proportionality” as there were reasons to doubt that the Study would actually “provide useful information” and whether it was “the least onerous way of addressing the concerns identified.”

The German Society Doctors Against Animal Experiments and the European Coalition to End Animal Experiments (ECEAE) had supported Honeywell’s appeal against ECHA’s decision. This is first case of the Board of Appeal annulling an ECHA decision to order an animal experiment.

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EU: EPAA lab tech award

For the first time in 2013, EPAA will grant a € 3,000 prize to a laboratory technician involved in implementing and raising awareness of Replacement, Reduction and Refinement of animal testing.

While most of the current Three Rs prizes and awards target scientists, much of the processes using animals for safety science are actually performed by laboratory technicians and animal care takers. The purpose of this prize is to target

those actually implementing alternative approaches to animal testing and raise awareness of their role for the day to day implementation of Three Rs principles and, in particular, for seizing opportunities for further Refinement.

The EPAA industry partners will sponsor a € 3,000 prize every other year, starting in 2013. The EPAA 3Rs Laboratory technician/care taker awardee will be invited to the EPAA annual conference to

receive the prize and briefly explain his or her contribution to the 3Rs.

Deadline for submission:
September 16, 2013

Further information: http://ec.europa.eu/enterprise/epaa/3_4_awards.htm

Jonathan Crozier
European Partnership for Alternative Approaches to Animal Testing (EPAA)

GER: Animal protection class actions introduced in three German states

In June the German states of North Rhine-Westphalia and Saarland both introduced animal protection class actions into state law. Registered animal protection organizations can now represent animals’ interests in class actions, balancing the rights of animal users to appeal against deci-

sions regarding animals. The new laws also give animal protection organizations participation rights and allow them to request a judicial review of authorities’ decisions that are relevant for animal protection. Thus, class actions will be the last resort and will probably only become

necessary in exceptional cases. In addition, the state of Saarland also decided to establish the post of an animal protection officer on a voluntary basis. The state of Bremen already introduced animal protection class actions in 2007.

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GER: *Bundesrat* introduces regulation for animal experiments

On June 7 the German Federal Council agreed to the draft regulation for the national implementation of the European Directive on the protection of animals used for scientific purposes (2010/63/EU) with changes. The regulation contains detailed rules on the housing, husbandry and use of experimental animals and complements the new German Animal Protection Law of February 2013. The rules lay out the purposes for which animal experiments may be performed,

the obligation to minimize the burden on the animals, the conditions for approval of experiments, the expertise required of involved persons, limitations for the use of certain animals, the obligation to appoint an animal protection officer, animal protection committees or obligations to produce records. New elements are that the public must be informed of approved animal experiments and that certain animal experiments must be officially evaluated retrospectively after their comple-

tion. In addition the Federal Institute for Risk Assessment is explicitly assigned to counsel the responsible authorities with regard to handling, husbandry or use of experimental animals as well as alternatives to animal experiments.

Decision and changes:
http://www.umwelt-online.de/PDFBR/2013/0431_2D13B.pdf
 Press release BMELV June 7, 2013

GER: Revised book on cell and tissue culture

The fully revised, extended, and newly illustrated 7th edition of the book *Zell- und Gewebekultur* (Cell and tissue culture) by Gerhard Gstraunthaler and Toni Lindl provides students of biology, medicine, pharmacy, or biotechnology as well as scientists and technical assistants with a comprehensive insight into cell and tissue culture in German language. The background information was expanded and relevant legal guidelines and references were updated. The practical pro-

ocols are accessible to beginners and provide useful tips for routine application as well as guidance on specific methods for the more advanced. New chapters on DNA profiling for the authentication of human cell lines and on serum-free cell culture were added; the chapter on methods to identify mycoplasma contaminations was extended. The authors aim to propagate a good cell culture practice by sensitizing readers to the importance of quality control and quality management.



Publisher:
 Springer
 Spektrum
 ISBN-13:
 978-3642331121

GER: Towards alternative methods in education in Eastern Europe

The German Society Doctors Against Animal Experiments (*Ärzte gegen Tierversuche e.V.*) has published a trilingual website in Russian, Ukrainian, and German to inform students and teachers of their Eastern European project in which institutes, mainly in the Ukraine, are provided with alternative teaching aids if they agree per contract to abstain from animal experiments in their study courses. Since the start of the project in 2008, 36 institutes in 15 Ukrainian towns have signed the contract and have

received laptops, beamers, multimedia programs, and videos in return. The Society estimates that the program currently reduces animal use by 35,000 animals per year.

The Society also cooperates with InterNICHE on projects in Russia, Uzbekistan, and Kyrgyzstan, has financed the production of educational films in Russian and has held press conferences to sensitize the public about alternative methods.

The new website gives details on the institutes that are participating in the program, provides information on alternative teaching methods, and lists arguments against animal experiments in education and research.

Further information:
<http://www.ukraine-projekt.de>

Press release
 Ärzte gegen Tierversuche e.V.
 June 28, 2013

INT: DNT4 – call for abstracts

The Fourth International Conference on Alternatives for Developmental Neurotoxicity Testing (DNT) is inviting the submission of abstracts on the following DNT topics:

- Development and use of alternative testing methods and strategies
- Automation of test methods
- Models of chemical-induced neurological deficits
- The impact of international legislation on chemical testing and data interpretation
- Toxicity pathways: Linking molecular events to adversity (AOP and PoT)
- Predictive molecular and cellular biomarkers of DNT
- Modeling gene/environment interactions that impact neurodevelopment
- Epigenetic changes and neural development

Abstract submission deadline: December 31, 2013

Conference date: May 12-14, 2014 – Philadelphia, PA at The Inn at Penn, A Hilton Hotel

See: <http://caat.jhsph.edu/dnt4> for more information

INT: Grants for research roadmaps for 3 human disease areas

Humane Society International (HSI) will soon be offering grants to credentialed scientists to prepare in-depth reviews including proposals for future research ‘roadmaps’ for three human disease areas, to be published in peer-reviewed journals. The reviews will critically evaluate the contributions and limitations of animal-based models of human diseases, and identify opportunities for progress through the application of 21st century paradigms, including understanding disease pathways using the growing toolbox of human biology-based models and technologies. Applicants will have a scientific PhD (or equivalent) and current or recent research experience in the academic, private or public sectors, as well as publications relevant to the disease area they propose to address.

HSI has already published a critical review of asthma research (Buckland, 2011) and reviews on Alzheimer’s and Parkinson’s diseases and motor neuron disease are in preparation. HSI is now

interested in further disease areas where the current research paradigm can be critically reviewed on a scientific basis and where a draft ‘roadmap’ can be envisaged using mainly contemporary human-specific models and technologies. With the aid of systems biology, disease pathways and networks can increasingly be researched by means of advanced clinical and *ex vivo* studies and sophisticated *in vitro* models using human cells (including induced pluripotent stem cells). For these 21st century techniques to achieve their full potential, HSI believes that a new paradigm will be needed in medical research and drug discovery: one that is less dependent on animal models, conceptually and in practice. A similar transition is already well underway in chemical toxicology (Stephens et al., 2012).

Three grants of up to US\$ 10,000 (or equivalent) will be payable to the successful applicants for writing and publishing each review. Further grants will

be available for disseminating the work at scientific conferences and workshops. In early September 2013, HSI will circulate a Request for Proposals relating to this project (closing date for applications will be mid-October).

For further information contact
Dr Gill Langley at: glangley@hsi.org

References

- Buckland, G. L. (2011). Harnessing opportunities in non-animal asthma research for a 21st-century science. *Drug Discov Today* 16, 914-927.
- Stephens, M., Barrow, C., Andersen, M., et al. (2012). Accelerating the development of 21st century toxicology: Outcome of a Human Toxicology Project Consortium workshop. *Toxicol Sci* 125, 327-334.

Adapted from HSI Advance Notice of Funding Opportunity May 2013



SUI: News from ALTEX

ALTEX proudly announces the winner of the ALTEX Award 2013: “Screening of Budesonide Nanoformulations for Treatment of Inflammatory Bowel Disease in an Inflamed 3D Cell-Culture Model” by Fransisca Leonard, Hussain Ali, Eva-Maria Collnot, Bart J. Crie-laard, Twan Lammers, Gert Storm, and Claus-Michael Lehr (ALTEX 3/2012). The prize of € 2,000 will be awarded to

the first author at the High Content Imaging (HCI) Systems in Safety Sciences Symposium in Mainz in October.

The Journal Citation Reports of 2012 released in June list ALTEX with an Impact Factor above 4 for the third year running (IF 2012: 4.093). We would like to thank all authors and reviewers for their valuable contributions that showcase the progress made in 3Rs research.

ALTEX now publishes uncorrected accepted manuscripts in full in the section “Online first” on the website www.altex-edition.org. The manuscripts are also indexed in PubMed as Epub ahead of print items and are linked to the respective pdfs on the ALTEX website.

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UK: CRACK IT Solutions funding

To maximize the value of CRACK IT Solutions the NC3Rs has introduced a funding scheme to catalyze partnerships in the development and/or validation of these novel technologies and approaches.

CRACK IT Solutions funding is only available to Solutions that have been submitted from an EU-based organiza-

tion/company and that have identified a potential collaborator as a result of the CRACK IT Solutions partnering process. Funding will not be available to new Solutions that have not been showcased on the CRACK IT website.

The funding available is up to a value of £ 30k inclusive of VAT per Solution

for projects of up to 12 months duration.

More information and forms at:
<http://www.crackit.org.uk/share/solutionsfunding>

Adapted from NC3Rs Newsletter
Issue 53, May 2013

UK: Michael Balls made Honorary Life President of FRAME

FRAME (Fund for the Replacement of Animals in Medical Experiments) has announced the resignation of its Chairman of Trustees Professor Michael Balls after 32 years, for personal reasons. The trustees gave a vote of thanks for his outstanding service. He remains honorary editor of the journal *ATLA* (*Alternatives to Laboratory Animals*) and of *PiLAS* (*Perspectives in Laboratory Animal Science*).

Professor Balls has received many awards and honors for his work in the search for alternatives to laboratory animals, both in the UK and overseas. He acted as an adviser to the British Government during the drafting and passage through Parliament of the Animals (Scientific Procedures) Act 1986 and was a founder member of the Animal Procedures Committee and of ERGATT (European Research Group for Alternatives in Toxicology Testing), and was the first Head of the European Centre for the Validation of Alternative Methods (ECVAM).

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Adapted from FRAME
Announcements
on June 3 and 18, 2013

UK: Nominations for the 2013 Lush Prize sought

Nominations for “outstanding contributions” to replacing animal use in product safety testing are now sought across the same five categories as last year: Science, Training, Lobbying, Public Awareness,

Young Researcher. Projects achieving their goals in the last twelve months particularly are sought. Individuals can nominate projects they like, or organizations can nominate themselves. Nominations

must be submitted by the closing date of July 15, 2013.

More information:
<http://www.lushprize.org/awards/>

USA: 2014 CAAT Science-based Refinement Awards: Call for proposals

Attention veterinarians, lab technicians, animal technicians, and all who work with laboratory animals: The Johns Hopkins Center for Alternatives to Animal Testing (CAAT) now is accepting proposals for the 2014 Science-based Refinement Awards (formerly the Animal Welfare Enhancement Awards).

The focus of these awards is to elicit scientific evidence to support the enhancement of the housing, handling and/or experimental situations for laboratory animals.

Deadline for Submission is September 30, 2013.

See <http://caat.jhsph.edu/programs/awards/AWE/2014/index.html> for more information.

USA: EPA announces plans for ToxCast Phase II release

EPA's Computational Toxicology (CompTox) effort uses innovative research that integrates advances in molecular biology, chemistry, exposure science, and computer science to more effectively and efficiently rank chemicals based on potential risks. Using CompTox approaches, thousands of chemicals can be screened effectively for risks at a small cost in a very short amount of time. One result from EPA's CompTox research is rapid chemical screening data from the Toxicity Forecaster (ToxCast, <http://epa.gov/ncct/toxcast/>) and the Toxicity Testing in the 21st century federal collaboration (Tox21, <http://epa.gov/ncct/Tox21/>). Other CompTox research results include high-throughput exposure predictive models, high quality chemical structure information linked to toxicity data, and computer simulated models (for example Virtual Embryo). All of this research can be used together to help better assess chemicals for potential risks to human health.

ToxCast is a multiyear, multimillion dollar effort that uses advanced high-throughput chemical screening to help understand how human biology is impacted by exposure to chemicals and to determine which exposures are the most likely to lead to adverse health effects. A large contributor to ToxCast is the Tox21 federal agency collaboration. Tox21 is using robotics technology to screen over 8,000 chemicals for potential toxicity. The Tox21 collaboration pools chemical research, data and screening tools from the Food and Drug Administration (FDA), the National Institute of Environmental Health Sciences/National Toxicology Program (NIEHS/NTP), and the National Institutes of Health (NIH) Center for Advancing Translational Sciences.

EPA has made significant progress since the initial ToxCast Phase I chemical data release in 2009. EPA has now completed Phase II screening which includes almost 2,000 chemicals in more than 650

high-throughput screening assays. Phase II chemicals are found in a broad range of sources including industrial and consumer products, food additives, touted “green” products, nanomaterials, and drugs that never made it to the market. Working with the other Tox21 federal partners, the screening of over 8,000 chemicals (these include the ToxCast chemicals) in almost 50 high-throughput screening assays is completed. EPA plans to publicly release the new Phase II high-throughput screening data in September 2013. EPA scientists are now working to analyze the new data and will publish scientific manuscripts about these results in the next few months. The first ToxCast Phase II paper was recently published (Sipes et al., 2013).

Once released, all available ToxCast chemical screening data can be queried and downloaded through the CSS Dashboard (<http://epa.gov/research/priorities/docs/css-dashboards-fact-sheet.pdf>) and the ToxCast database (ToxCastDB, <http://>



actor.epa.gov/actor/faces/ToxCastDB/Home.jsp). The CSS Dashboard and ToxCastDB provide available ToxCast data with links to chemicals, assays, genes, pathways, and endpoints. Using ToxCast, EPA researchers have also evaluated almost 1,000 chemicals in approximately 50 endocrine related high-throughput assays. EPA is working with partners to determine if ToxCast data can be used to help prioritize chemicals for EPA's Endocrine Disruption Screening Program. EPA is also evaluating ToxCast data to see if it can help prioritize chemicals regulated under the Toxic Substance Control Act (TSCA). If successful, ToxCast data could help inform requests for further testing data on High Production Volume (HPV) industrial chemicals.

EPA's CompTox effort actively uses partner outreach to help make this new chemical information more understandable and useable to those making decisions about chemicals. After the September release of ToxCast Phase II chemical screening data, CompTox is planning to use workshops, webinars, and training to showcase the data and to ask for feedback about how CompTox research can be used to inform decisions. CompTox also hosts monthly CompTox com-

munities of practice (<http://epa.gov/ncct/partners.html>) which feature a presentation about an upcoming research topic of interest. CompTox has active partnership agreements with hundreds of external stakeholders.

Please contact Monica Linnenbrink if you are interested in being a part of the outreach activities planned for EPA's CompTox research effort.

Timeline for ToxCast & Tox21 data release

- Ongoing: ToxCast data analysis. Writing and publishing scientific papers with data analysis results.
- March 2013: Pre-publication release of ToxCast and Tox21 data to EPA partners.
- April 23, 2013: EPA hosted a webinar for partners. EPA scientists demonstrated how to access & navigate pre-published ToxCast and Tox21 data. A video of the webinar was provided to partners who could not participate in the scheduled webinar.
- September 2013: Public release of ToxCast Phase II data through an online "Chemical Safety for Sustainability Dashboard". EPA will announce the availability of the data and encour-

age partners to submit ideas (through "Challenges") about how to use Phase II data to inform decisions.

- October 2013-March 2014: Outreach activities for interested external partners. This will include webinars, trainings, briefings, and more.
- May 2014: EPA will hold a ToxCast and Tox21 Data Analysis Workshop. EPA partners, external organizations, and internal EPA staff are encouraged to present ideas on using ToxCast and Tox21 data to assess chemical risk.

Reference

Sipes, N. S., Martin, M. T., Kothiyia, P., et al. (2013). Profiling 976 ToxCast chemicals across 331 enzymatic and receptor signaling assays. *Chem Res Toxicol* 26, 878-895.

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USA: NIH to retire 90% of chimpanzees from research

The National Institutes of Health (NIH) have announced that they will greatly reduce the use of chimpanzees in NIH-funded biomedical research. Up to 50 chimpanzees will be kept but not bred for future biomedical research that meets the IOM principles and criteria. Research projects using NIH-owned or -supported chimpanzees that do not meet the IOM principles and criteria shall be wound down in a way that preserves the research and minimizes the impact on the animals.

The retired chimpanzees shall join the Federal Sanctuary System operated by Chimpanzee Haven upon resources and space availability in the sanctuary system. This will require some technical changes in NIH's legal authority in putting financial resources toward retiring chimpanzees and caring for them. While broadly accepting the recommendations of ethologically appropriate facilities, NIH did not accept, due to the lack of scientific consensus, the recommendation that the

primary living space of research chimpanzees be at least 1,000 square feet per chimpanzee. NIH will engage chimpanzee behavior and facilities experts to determine the appropriate minimum space requirement for research chimpanzees.

Adapted from National
Institutes of Health
News Release
June 26, 2013



USA: Toxicogenetics Challenge open

The NIEHS-NCATS-UNC DREAM Toxicogenetics Challenge (<http://www.niehs.nih.gov/funding/challenges/>) was announced by Sage Bionetworks (<http://sagebase.org>) on June 11, 2013. The objective of this three-month Challenge is to build predictive models of cytotoxicity based on data obtained from *in vitro* studies in which lymphoblastoid cell lines derived from 884 individuals were exposed to 156 environmental toxicants and drugs.

This computational Challenge aims to engage diverse communities of scientists

in competitively solving one or both of two related subchallenges. In subchallenge 1, participants are asked to model interindividual variability in cytotoxicity based on genomic profiles in order to predict cytotoxicity in unknown individuals. In subchallenge 2, participants are asked to predict population-level parameters of cytotoxicity across chemicals based on structural attributes of compounds in order to predict median cytotoxicity and mean variance in toxicity for unknown compounds. Interested individuals can sign up to participate.

The Challenge closes on September 15, 2013, and the top-scoring team(s) will be announced in November 2013. The winner of each subchallenge will be invited to speak at the 2013 DREAM conference to be held on November 8-12 in Toronto, Canada in conjunction with the Sixth Annual RECOMB/ISCB Conference on Regulatory and Systems Genomics.

NTP listserv
June 12, 2013