News

EU: AXLR8 progress report available

The coordination action AXLR8, which runs under the 7th European RTD Framework Programme, has published its 2012 Progress Report entitled "Alternative Testing Strategies – Progress Report 2012 & AXLR8-3: Workshop Report on a Roadmap to Next Generation Safety Testing under Horizon 2020". It details achievements of the EU, Member States, and other countries working to develop advanced tools for toxicological safety assessment together with recommendations from AXLR8-3 workshop break-out groups in relation to the upcoming EU Framework Program "Horizon 2020," which will be launched in January 2014.

The report may be downloaded and paper copies may be ordered at http://axlr8.eu/

EU: Proposals to test substances examined by ECHA

ECHA has examined all proposals to test substances submitted by the first REACH Registration Deadline and has issued draft or final decisions to companies. This is an important step in the REACH process – making sure that data gaps are filled but at the same time avoiding unnecessary testing on animals.

The REACH Regulation requires registrants to submit proposals for testing to ECHA when they identify a data gap for certain information requirements. ECHA has the obligation to examine all the proposals in a certain timeframe. For all testing proposals submitted by the first registration deadline of November 30, 2010 ECHA had to prepare a draft decision by December 1, 2012. This deadline has been met successfully.

A total of 571 dossiers (with altogether 1,184 individual testing proposals) have been examined. Nearly 130 cases were terminated due to the withdrawal of the proposals, testing already being initiated or for other reasons. Draft decisions were issued in 436 cases, of which 146 have already resulted in a final decision. In the other 290 cases the decision making procedure will continue in 2013. In 24 of these cases, the proposals for reproduction toxicity tests have been referred to the Commission because the Member State Committee did not reach agreement on them.

For the remaining 14 cases the examination of the testing proposals has been suspended due to the non-compliance of the substance identity information. Instead, a compliance check decision has been prepared. In these cases, the deadline of December 1 does not apply. There are also several other cases where the involved registrants have been requested to clarify the identity of the substance first before the draft decision on testing proposal can be processed further.

The purpose of the testing proposal examination is to ensure that the tests proposed by the registrants are necessary and adequate for meeting the REACH information requirements. ECHA checks recognized sources of information and organizes consultation of third parties on all testing proposals involving vertebrate animals so that unnecessary animal testing can be avoided. A full picture of the progress in evaluation during 2012 will be presented in the annual report, which is due to be published by the end of February 2013.

Adapted from
ECHA/PR/12/32
December 5, 2012

GER: Macaque experiments to continue in Bremen

The Higher Administrative Court of Bremen ruled that experiments on macaques may be continued at the University of Bremen and that no further revision of this decision is possible.

The Senate of Bremen had decided in 2007 that the experiments on macaques performed in the laboratories of Prof. Andreas Kreiter should be terminated. Subsequently, the public health authority of Bremen had declined approval of the researcher's 2008 application to continue the experiments on macaques and rats. During the ensuing legal dispute the neurobiologist had been allowed to continue experiments which involve implanting electrodes into the brains of macaques, fixating them during the experiments, and rewarding their cooperation by dispensing limited volumes of liquid through a straw. Kreiter's new application to continue the experiments submitted in 2011 had been declined by the public health authority of Bremen. An appeal was submitted to the Higher Administrative Court which on December 11, 2012 overturned the health authority's decision and licensed the experiments until 2014.

Various German animal protection organizations voiced their discontent with the decision, stating that experiments that subject animals to repeated, severe distress should not be approved and that in such cases the protection of animals, which is named a state goal in the German constitution, should be given precedence over the freedom of research, which is declared a basic right in the same. In 2006 applications to perform similar experiments were declined in Berlin and Bavaria.

sva

GER: New Animal Protection Law passes *Bundestag*

On December 13, 2012 the Lower House of German Parliament (*Bundestag*) passed the draft of the third revision of the national Animal Protection Law with the vote of the ruling parties. The draft is highly criticized by animal protection organizations such as the *Deutscher Tierschutzbund* and its 700 affiliated organization, as it not only continues to allow animal handling practices such as castration of piglets without aesthesis (until 2019), branding of horses, fur farming, and display of wild animals in circuses, but also does not make use of the full scope of improvements allowed by Directive 2010/63/EU on the use of animals for scientific purposes, such as the option to ban experiments on non-human primates and to promote animal-free research by declaring this a priority.

Directive 2010/63/EU was required to be translated into the national law of all EU Member States by November 10, 2012 and to be applied from January 1, 2013. The Upper House of German Parliament (Bundesrat), which could block the new law, is only scheduled to deal with it in February 2013. The Bundesrat made numerous requests for changes of the draft in July, most of which are not included in the current version.

sva

GER: Number of animals used for scientific purposes rises again

The number of experimental animals used in Germany in 2011 increased over the 2010 count by about 55,000 animals (2%). The total number of animals, which has risen for the eighth year in succession, is 2,911,705.

The increase is mainly due to a further increase in the number of mice by 73,000 to 2,036,606 (70% of total animal use). This is in part due to a further increase in the number of genetically modified animals, which now make up 25% of total animal use and of which 95% are mice.

Rats (14%), fish (7%), birds (4%), rabbits (3%), and pigs (0.5%) are the other most commonly used animals. The number of monkeys, dogs, and cats used is slightly lower than in the previous year.

35% of animal experiments are conducted in basic research; 16% for research and development in human, dental, and veterinary medicine; 9% for the production and quality control of products for human, dental, or veterinary medicine; and 6% for toxicological or other safety tests. Other purposes include diagnosis of disease, efficacy tests for pesticides, and education.

The number of animals used for toxicological or other safety tests was slightly higher than in 2010.

The full statistics published by the German Federal Ministry of Food, Agriculture and Consumer Protection can be found at: http://bit.ly/UHErzE

sva

GER: Animal Protection Prize for carcinogenicity assay

On December 13, 2012 the Federal Ministry of Food, Agriculture and Consumer Protection awarded the 31st Animal Protection Prize to Dr Ralf Herwig of the Max Planck Institute for Molecular Genetics in Berlin. The prize is endowed with € 15,000.

Dr Herwig received the prize for the development of a systems biology approach to assess the carcinogenic potential of chemicals in the liver. Using experimental results from microarrays of human liver stem cell cultures treated with an array of chemical substances, a computer simulation of the complex metabolic processes involved in the metabolism of chemicals and in the development of cancer was constructed. The procedure has undergone a double blind prevalidation study at the European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM) to determine its reliability and reproducibility for replacing chronic carcinogenicity studies in rodents.

sva

GER: Prize for animal-free contact allergen test

On October 8, 2012 the Ministry of Rural Areas and Consumer Protection Baden Württemberg, Germany announced the award of its State Research Prize for Alternative and Complementary Methods for Animal Testing to a team of scientists from the university clinics of Freiburg and Mannheim. Prof. Dr Stefan Martin and PD Dr Hermann-Josef Thierse with Dr Lisa Dietz and Dr Philipp Esser developed a human T cell activation assay that enables the identification of potential contact allergens. The assay is an animal-free alternative to the Local Lymph Node Assay (LLNA) generally performed in mice. The prize of € 25,000 was awarded in Stuttgart by Minister for Consumer Protection Alexander Bonde. The assay is described in the following article:

Dietz, L., Esser, P. R., Schmucker, S. S., et al. (2010). Tracking human contact allergens: From mass spectrometric validated chemicalpeptide interactions to chemical-specific naïve human T cell priming. *Toxicol Sci 117*, 336-347.

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INT: Report on applicability of alternatives in regulatory frameworks

The International Cooperation on Cosmetics Regulation (ICCR) has issued a report on "Applicability of Animal Testing Alternatives in Regulatory Frameworks Within ICCR Regions." The report "provides an overview of processes and mechanisms for the use of alternatives in human safety assessments of cosmetic products and ingredients in the four ICCR jurisdictions."

The report is available at: http://www.fda.gov/downloads/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/UCM320464.pdf

The ICCR is made up of representatives of cosmetic regulatory authorities from the United States, Japan, the European Union, and Canada. The goal of the ICCR framework is to maintain the highest level of global consumer protection while minimizing barriers to international trade.

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INT: New OECD Test Guidelines for endocrine disruptor testing

The Organisation for Economic Co-operation and Development (OECD) has officially adopted two test guidelines for test methods to identify substances with the potential to affect the function of the endocrine system. Both test guidelines describe in vitro methods that do not use animals, and the tests are appropriate for use in the U.S. Environmental Protection Agency (EPA) Endocrine Disruptor Screening Program.

The new test guidelines are available on the ICCVAM website:

– OECD Test Guideline 457: "BG1Luc Estrogen Receptor Transactivation Test Method for Identifying Estrogen Receptor Agonists and Antagonists" is available at: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECD-TG457-508.pdf
– OECD Test Guideline 455: "Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists" is available at: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECD-TG455-2012-508.pdf

Test Guideline 457 describes the BG1Luc estrogen receptor (ER) transactivation (TA) assays to detect ER agonist and antagonists and provides performance standards for each assay. The test guideline was based on data from an international validation study coordinated by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The validation study included laboratories in the United States, Japan, and Italy.

NICEATM worked closely with the EPA to usher this method through the OECD nomination and adoption process. The adoption of Test Guideline 457 means that these methods may now be used in the 34 member countries of the OECD. In July 2012, the EPA announced its acceptance of the BG1 method as an alternative to the HeLa9903 TA assay in response to a recommendation by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

Test Guideline 455 has been updated to include both the BG1 and HeLa9903 methods, and now describes general characteristics of stably transfected transactivation in vitro assays to detect ER agonists. This performance-based test guideline also provides standards for development of new test methods of this type. These standards include a harmonized list of reference chemicals that should be tested during assay development, as well as performance standards that should be met by successful assays.

Posted on http://www.alttox.org
by Catherine Sprankle
November 7, 2012

INT: QSAR guidance document for pesticides

The U.S. Environmental Protection Agency Office of Pesticide Programs (U.S. EPA/OPP) and Health Canada's Pest Management Regulatory Agency (PMRA) have cooperated on the development of a guidance document on the use of Quantitative Structure Activity Relationships [(Q)SAR] for pesticide risk assessors. This document has been developed under a North American Free Trade Agreement Technical Working Group (NAFTA TWG) project, 21st Century Toxicology: Integrated Approaches to Testing and Assessment.

The NAFTA TWG (Q)SAR Guidance Document provides an introduction to (Q)SAR and a flexible framework to assist with problem formulation for (Q)SAR, assessing the adequacy of predictions, and incorporating predictions into weight of evidence based assessments of pesticides. While the (Q)SAR Guidance Document was not designed to be a step-by-step manual, it provides useful guidance to evaluators who are reviewing predictions included in pesticide submissions or who are using (Q)SAR to help identify additional data requirements for pesticides, metabolites or degradates. Moreover, it also supplements, but does not replace, existing (Q)SAR guidance documents from the Organisation for Economic Cooperation and Development (OECD), the European Chemicals Bureau and other agencies.

The NAFTA TWG (Q)SAR Guidance Document is currently available for download at: http://www.epa.gov/oppfead1/international/naftatwg/guidance/qsar-guidance.pdf

Kristie Sullivan
Secretary, ASCCT
http://www.ascctox.org

INT: OECD updates training material for QSAR Toolbox

The tutorials and videos for the QSAR Toolbox Version 3.0 have now been updated according to the new version of the QSAR Toolbox to help the user building categories that are mechanistically and structurally robust to maximize success in filling data gaps for the endpoint of interest. Mid 2013 the OECD is planning to release additional training material.

http://www.oecd.org/chemicalsafety/assessmentofchemicals/theoecdqsartoolbox.htm

Kristie Sullivan
Secretary, ASCCT
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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 in July 2013. 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.

For information and application forms please contact:

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e-mail: las@uu.nl
http://www.uu.nl/lascourse

UK: LUSH prizes awarded

The 2012 winners of the first LUSH Prize announced on November 15, 2012 in London were as follows:

Science Prize:
– Institute for Health and Consumer Protection, Italy (£ 50,000) for their work on toxicity pathways in hepatotoxicology and developmental toxicology

Lobbying Prize:
– Humane Society International, USA (£ 40,000) for their work on removing animal tests from the EU's non-food pesticide regulations
– Federation of Indian Animal Protection Organisations (FIAPO), India (£ 5,000) for their research and lobbying on animal testing in India
– People for the Ethical Treatment of Animals (PETA) India (£ 5,000) for their work with Indian regulators on a cosmetics testing ban

Training Prize:
– Institute for In Vitro Sciences, USA (£ 25,000) for their vital work on training researchers in non-animal methods from Brazil to Japan
– InterNICHE, (£ 25,000) for their work in training in former Soviet states, South America and Africa

Public Awareness Prize:
– Japan Anti-Vivisection Association, Japan (£ 30,000) for their successful campaign to persuade Shiseido to abandon animal testing
– Decipher Films, Canada (£ 10,000) for their feature film "Maximum Tolerated Dose" on animal testing
– VITA Animal Rights Centre, Russia (£ 10,000) for their work on awareness raising with the Russian media

Young Researcher Prize:
– Elizabeth Woehrling, UK (£ 12,500) for her work on the development of a new *in vitro* test for neurotoxicity
– Felix Rivera-Mariani, USA (£ 12,500) for work on expanding an existing non animal test into new areas
– Chiara Scanarotti, Italy (£ 12,500) for her work on skin sensitization and chemical mixtures
– Line Mathiesen, Denmark (£ 12,500) for her work on studying the impact of toxics on placental tissue

The Lush Prize is a collaboration between Lush and Ethical Consumer. Lush is a campaigning manufacturer and retailer of fresh handmade cosmetics with shops in 49 countries. Ethical Consumer Research Association is a UK-based research and consultancy co-operative focused on working with companies and consumers around effective ethical choices.

http://www.lushprize.org

UK: NC3Rs invites submissions for project and pilot study grants

The project grant scheme is the NC3Rs' main route for funding 3Rs research. It is an annual response mode scheme for hypothesis-driven and applied research. Awards can be for up to 36 months with the amount requested dependent on the science; typically in the region of £ 300k. Applications are invited from UK establishments for research project grants to support the development and application of the 3Rs.

Deadline: February 5, 2013
More information: http://www.nc3rs.org.uk/page.asp?id=57

The first pilot study grants were awarded in 2011 alongside the project grants. It is an annual response mode competition for proof-of-concept studies which can provide the preliminary data for subsequent, more substantive applications. Awards are limited to a maximum of £ 75k and 12 months duration. Applications are invited from UK establishments for pilot or proof of concept studies, to provide preliminary data for a subsequent, more substantive application that will support the development and application of the 3Rs.

Deadline: February 5, 2013
More information: http://www.nc3rs.org.uk/page.asp?id=1642

Adapted from NC3Rs e-newsletter
October 26, 2012

UK: FRAME launches PiLAS – Perspectives in Laboratory Animal Science

FRAME has launched a new and unique way of improving the quality of discussion about issues raised by animal experimentation and the Three Rs. FRAME's new initiative is called *Perspectives in Laboratory Animal Science (PiLAS),* and its primary aim is to offer professionals in all relevant fields an opportunity to share their expertise, knowledge, and ideas concerning the scientific, ethical, economic, and logistical aspects raised by laboratory animal use. It will take the form of a stand-alone supplement in each issue of FRAME's scientific journal *ATLA*, but is also freely available via a new website (http://www.atla.org.uk).

Discussion about animal experimentation can often be extremely polarized, but the intention is to take account of all reasonable points of view, and not to distort the coverage to support any particular stance. It will, however, promote the Three Rs philosophy put forward in 1959 by W. M. S. Russell and R. L. Burch in *The Principles of Humane Experimental Technique*. The initial plan is to have the following main sections: Opinion; Current Dilemmas; In-depth Discussions; The Wisdom of Russell and Burch; Points of View; News; Comments and Feedback.

PiLAS has been made possible by a grant from the Phoebe Wortley Talbot Charitable Trust.

FRAME Communications Team
November 30, 2012

USA: New U.S. Consumer Product Safety Commission policy on animal testing

A rule published by the U.S. Consumer Product Safety Commission (CPSC) codifies the statement of policy on animal testing that provides guidance for manufacturers of products subject to the Federal Hazardous Substances Act (FHSA) regarding replacement, reduction, and refinement of animals. Codification of this policy is intended to make CPSC's animal testing policy and test methods recommended by ICCVAM and accepted by CPSC more transparent and accessible to interested parties.

The rule was published in the Federal Register of December 10 (77 FR 73286). The rule includes comments received on the proposal and CPSC responses to the comments. The rule also includes the relevant amendments made to the text of 16 CFR part 1500. The statement of policy is effective January 9, 2013.

The rule is available on the ICCVAM website at:
http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/CPSC/CPSC-FR-2012-29260.pdf
or
http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/CPSC/CPSC-FR-2012-29260.htm

In a related notice, the CPSC announced amendments to its regulations on the CPSC's animal testing methods under the FHSA. The announcement, also published in the Federal Register of December 10 (77 FR 73290) includes comments received on the proposed rule and CPSC responses to the comments. The rule also includes revisions to animal testing regu-

lations and explanations of the rationale for the revisions. The rule takes effect January 9, 2013.

The rule is available on the ICCVAM website at:
http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/CPSC/CPSC-FR-2012-29258.pdf
or
http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/CPSC/CPSC-FR-2012-29258.htm

The FHSA (15 U.S.C. 1261-1278) requires appropriate cautionary labeling to alert consumers to the potential hazards that certain hazardous household products may present. These include products that are toxic, corrosive, irritants, flammable, combustible, or strong sensitizers. The changes to the FHSA announced today clarify the criteria used for classification of substances as "highly toxic," "toxic," "corrosive," "irritant," "primary irritant," and "eye irritant." The changes emphasize that the use of *in vitro* and other alternative test methods, including a weight-of-evidence approach, and prior human experience are recommended over in vivo animal tests wherever possible. Furthermore, the CPSC reiterates its preference for reliable human experience over animal test data.

CPSC has also established a page on its website regarding ICCVAM recommendations and new developments in test methods that avoid or further reduce or refine animal testing. The page is located at: http://www.cpsc.gov/BUSINFO/animaltesting.html

According to the ICCVAM Authorization Act, ICCVAM member agencies should promote and encourage the development and use of alternatives to animal test methods for regulatory purposes. Since the establishment of ICCVAM, the CPSC has approved, where applicable, recommendations made by ICCVAM to reduce and refine animal testing applicable to test methods under the FHSA. A table summarizing U.S. and international regulatory acceptance of alternative test methods, which includes methods recommended by ICCVAM applicable to testing under the FHSA, is available on the ICCVAM website at: http://iccvam.niehs.nih.gov/about/accept.htm

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USA: Joanne Zurlo now North American Editor of ALTEX

Joanne Zurlo, PhD has been named as the North American Editor of ALTEX. Joanne received her Ph.D. in Basic Medical Sciences from New York University in 1979, with a concentration in biochemistry and chemical carcinogenesis. She served on the faculty at Dartmouth Medical School in Hanover, New Hampshire and at the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. She was the Associate Director of the Johns Hopkins Center for Alternatives to Animal Testing (CAAT) from 1993-2000 and was a member of the Institutional Animal Care and Use Committee. From 2000-2010, she was the Director of the Institute for Laboratory Animal Research (ILAR) at the National Academies in Washington, DC, where she expanded international activities and harmonization discussion, directed publication of the quarterly

ILAR Journal, and spearheaded and coordinated the development of special reports related to Laboratory Animal Welfare and Guidelines, including the 8th Edition of the Guide for the Care and Use of Laboratory Animals. Joanne returned to Johns Hopkins CAAT in April 2010 as the Director of Science Strategy. In this capacity she directs CAAT's refinement efforts, including the Science-based Refinement Grants program and participates in other CAAT strategic activities. Dr Zurlo has authored over 50 publications in scientific books and journals and is an active member of AAAS, American Association for Laboratory Animal Science, American Association for Cancer Research, and the Society of Toxicology (SOT). She served as the Chairperson of the Committee on Public Communications for SOT, was the president of the In Vitro Specialty Section for 1997-1998 and was on the Education Subcommittee for K-12 Education from 2002-2005. She also serves on the boards of the Scientists Center for Animal Welfare and the William and Charlotte Parks Foundation for Animal Welfare, and on the editorial board for the *Journal of Applied Animal Welfare Science* and the online publication *The Enrichment Record*.