News

EU: Revised version of DB-ALM online

The second release of the DB-ALM went online in October 2016. The former website and search interfaces for all data sectors (e.g. Projects and related information, People and Institutions active in the field of 3Rs) are now replaced with a new, revised version. Further enhancements, made to improve the search, display and data sharing by public users, include:

- A unique URL is generated for each search, providing a direct link to the selected page, that can be bookmarked and shared through e-mail or social media.
- Enhanced possibilities for sorting search results by key features of the methods.
- A tutorial movie illustrating the main aspects of the DB-ALM, that can be accessed through a blue tab on the right of the screen.
- A feedback form, that you are kindly invited to use in order to help us to continuously improve the service, that can be accessed through a blue tab next to the Tutorial.

More information on latest achievements of the database service is accessible as a Bi-annual Report at http://bit.ly/2iE2cvH.

Adapted from DB-ALM newsletter November 30, 2016

GER: Number of animals used for scientific purposes steady

In Germany, 2,799,961 procedures were performed on animals for scientific purposes in 2015 compared to 3,361,863 in 2014. However, the apparent difference lies in a lower reporting – by 483,000 – of the use of fish larvae in 2015. If these are taken out of the 2014 count, the number of procedures in the two years is comparable.

The procedures were most commonly performed on mice (2 million; 72.6%), rats (326,000; 11.7%), fish (201,000; 7.2%) and rabbits (112,000; 4.0%). Among numerous other species, 4,491 scientific procedures were performed on dogs, 1,112 on cats and 3,141 on monkeys. Especially dogs, cats, monkeys and African clawed frogs (Xenopus) were re-used. The total number of animals used for experimental procedures was 2.75 million.

The number of monkeys used in animal experiments increased by 943 (64%) to 2,424 animals; most monkeys (82%, all of these cynomolgus monkeys) were imported from Asia or Africa. Of the imported monkeys, none were wild-caught, but 26% were F1 generation, i.e., born from wild-caught parents.

58.7% of procedures were attributed to basic research, 22.5% to regulatory testing and routine production, and 13.6% to applied research. Other purposes included maintenance of colonies of established genetically altered animals (1.9%), higher education (2%), preservation of species (1%), and protection of the natural environment (0.2%).

Of the total procedures performed in regulatory testing and routine production, 37% were for quality control (e.g. batch safety and potency testing, and pyrogenicity testing), 7.2% for other efficacy and tolerance testing, 15% for routine production (e.g. blood based products and monoclonal antibodies) and 41% for toxicity and other safety testing including pharmacology. Toxicity and safety testing procedures thus made up 9% of all procedures on animals. Within the toxicity and safety testing procedures, the highest number of procedures were performed for pharmacodynamics (35%), kinetics (15%) and ecotoxicity (12%). 70% of procedures performed for regulatory use and routine production control were performed under legislation for medicinal products for human use and 9.7% under medical devices legislation, followed by industrial chemicals legislation (8%), medicinal products for veterinary use (6%) and plant protection products (5%) among others.

Of all animal procedures 112,000 (4%) were deemed severe, 17% moderate, 43% mild and 35% non-recovery. Most of the procedures attributed to basic research (87%) were non-recovery or mild with 1% (19,500) severe procedures. For translational procedures 66% were non-recovery or mild with 2.4% (9,269) severe procedures. However, regarding procedures for regulatory use or routine production purposes 65% of experiments were non-recovery or mild but 13.1% (82,500) were severe. These were mostly done in mice and mostly for batch potency testing. Regarding toxicity testing within the category regulatory use or routine production purposes, two thirds of procedures were deemed mild; severe experiments were performed mostly for acute and subacute toxicity testing, pharmacodynamics and ecotoxicity testing.

1.1 million procedures were performed with genetically modified animals (40% of total procedures), mostly mice; of these 13% (5% of total procedures) had a harmful phenotype.

More information: http://bit.ly/2iINVyd

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GER: New website on understanding animal research

The alliance of German scientific organisations, which includes Alexander von Humboldt Stiftung, Deutsche Forschungsgemeinschaft (DFG), DAAD, Fraunhofer Institut, Helmholtz Gemeinschaft, Hochschulrektorenkonferenz, Leibniz Gemeinschaft, Leopoldina, Max Planck Gesellschaft, Wissenschaftsrat, has started a new German-language website termed Tierversuche verstehen (Understanding animal experiments; https:// www.tierversuche-verstehen.de/), which aims to provide factual information on animal experiments to the public and media. The website includes a section on alternatives to animal experiments, which briefly explains the different approaches to alternative methods and introduces institutions in Germany that support alternatives to animal experiments. A section on ethics is also included. The website also includes infoboxes for different target groups and materials such as videos and graphs. A news alert informs readers of new information added to the website. Readers can also ask questions via a form and can leave comments.

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GER: BfR seeks experts for national committee

The BfR has published a call for a Pool of Experts for the National Committee for the Protection of Animals Used for Scientific Purposes for the Federal Republic of Germany.

The Pool of Experts supports the "National Committee for the Protection of Animals Used for Scientific Purposes" for the Federal Republic of Germany at the fulfillment of its legal duties, i.e., advising the competent authorities and animal welfare bodies on matters dealing with laboratory animals and animal experimentation. The goal of the National Committee is to publish scientifically grounded and independent recommendations to promote a harmonized interpretation and implementation of the German Animal Welfare Act (*TierSchG*). The Pool of Experts allows the National Committee to retrieve the needed expertise to advise the competent authorities and animal welfare bodies in the most flexible and efficient way, as well as in compliance with high scientific standards.

The required experts will be scientists with expertise in the fields of natural sciences, law, human and veterinary medicine as well as ethics. The expertise of animal caretakers in a leading position with a state-approved master craftsman degree ("*Meister-titel*") in research and clinics is also required.

The main criterion to be nominated for the Pool of Expert is the proof of expertise in the respective area, which can be determined by publications in peer-reviewed national and international journals as well as by professional experience of several years in the respective field. Additional criteria are further qualifications such as specialist training for medical doctors as well as experience in committee and review work. The experts work closely with the National Committee and support its members with their expertise. If experts are needed for a specific topic, the National Committee will retrieve those matching the requested profile from the pool. The most suitable experts will be chosen by using additional criteria (e.g. knowledge of specific animal experimental methods, particular animal species or legal topics) relevant for the specific question and will be contacted to check their availability. Hence, the nomination for the Pool of Experts does not automatically imply that an expert will be active as an expert for the National Committee.

The work as an expert for the National Committee is honorary.

Call opens: February 1, 2017 More information: http://bit.ly/2immCvA

> Adapted from BfR newsletter November 3, 2016

GER: First Hamburg research prize on alternative methods awarded

The first prize of the state of Hamburg for the "Promotion of Research on Replacement and Complementary Methods to Animal Testing" was awarded jointly to Christopher Weidner and the Bf3R team as well as to Marcel Leist from the University of Konstanz on December 9, 2016. The biannual prize is endowed with €20,000.

The method developed by Christopher Weidner and team enables scientists to choose the animal or alternative method that will best reflect the human situation to be investigated based on the analysis of systems biology data. Marcel Leist received the prize for the development of a replacement method to investigate the toxic effects of chemicals on cells of the human nervous system *in vitro*, see article on p. 75-94.

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GER: Hesse Animal Protection Research Prize awarded

On November 16, 2016 Christina Spohr of the Paul-Ehrlich-Institute in Langen was awarded the Hesse Animal Protection Research Prize for her PhD thesis in which she developed a method to reduce the number of animals and the severity of regulatory potency tests for tuberculins, which are used for the diagnosis of tuberculosis. The biannual prize is endowed with \notin 14,000.

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HRV: InterNICHE alternatives seminar for Government of Croatia and ethical committees

A full-day seminar titled "Best practice and alternatives to animal experiments in education and training" was held in Zagreb on October 24, 2016 at the Ministry of Agriculture of the Government of Croatia. The event was a collaboration between InterNICHE, Animal Friends Croatia (Prijatelji Životinja) and the Ministry of Agriculture. Around 30 participants from across the country attended, including Ministry officials, teachers and representatives of local ethics committees from different universities. The program was developed by InterNICHE and Animal Friends, an InterNICHE Partner organisation.

There has been some positive progress in Croatia during the past 2 years as universities and ethical committees take alternatives more seriously and decline some requests for harmful animal use, guided by the existing 2006 Animal Protection Act and the draft new Animal Protection Act. Resources produced in Serbia are now being shared with the participants in Croatia. These include a workbook for practical classes in physiology, produced by the Faculty of Medicine at the University of Belgrade. This publication guides the learning of physiology through the use of a range of alternatives, and had its origin in good campaigner-teacher networking at earlier ORCA outreach in the country. Harmful animal use at primary and secondary level is already banned in Croatia.

Collaboration between InterNICHE and Animal Friends will continue, with a view to further progressing the replacement of harmful animal use in higher education. The outreach was supported by the International Association Against Painful Experiments on Animals (IAAPEA).

> Adapted from InterNICHE Newsletter December 9, 2016

INT: OECD publishes guidance on IATA

To standardize the evaluation of IATA in regulatory decisionmaking, the OECD has developed guidance to provide principles and templates for reporting defined approaches and individual information sources. A second guidance has been developed to illustrate how the reporting templates can be used to document a number of defined approaches (and information sources used within) in the area of skin sensitisation.

 Guidance document on the reporting of defined approaches to be used within integrated approaches to testing and assessment. Series on Testing & Assessment No. 255. ENV/JM/MO-NO(2016)28. http://bit.ly/2hGPCgQ

• Guidance document on the reporting of defined approaches and individual information sources to be used within integrated approaches to testing and assessment (IATA) for skin sensitisation. Series on Testing & Assessment No. 256. ENV/JM/MO-NO(2016)29. http://bit.ly/2e5b9zt

• Annex I: Case studies to the guidance document on the reporting of defined approaches and individual information sources to be used within integrated approaches to testing and assessment (IATA) for skin sensitisation. Series on Testing & Assessment No. 256. ENV/JM/MONO(2016)29/ANN1 http://bit. ly/2hZh07e

 Annex II: Information sources used within the case studies to the guidance document on the reporting of defined approaches and individual information sources to be used within integrated approaches to testing and assessment (IATA) for skin sentitisation. ENV/JM/MONO(2016)29/ANN2. http://bit.ly/2im8QZL

Adapted from http//www.oecd.org

IRAN: InterNICHE Partners in Iran jointly win 2016 Lush Prize

The Iranian Anti-Vivisection Association (IAVA) has jointly won the 2016 Lush Prize for their work to replace animal experiments and implement alternatives in education and training (see UK news).

IAVA is a small but active organization and the only one in Iran that addresses animal experimentation. It works within a very challenging environment where campaigning is not typical, and where animals, especially dogs, are often seen very negatively. With a predominantly academic membership, it has been campaigning successfully for replacement alternatives, working with veterinary and other faculties since being founded by Dr Ramak Roshanaie 6 years ago.

IAVA has held seminars and multimedia exhibitions of alternatives at universities and academic conferences across the country. Its members meet with university deans, teachers and students nationwide to demonstrate, train and help introduce alternatives. It recently held Iran's first academic animal rights panel, and has been lobbying the Ministries of Education, Health and Science to change the education system nationally. IAVA also addresses the use of dissection at some primary and secondary schools, and promotes alternatives in the fields of research and testing.

Replacement has been achieved in a number of practical classes in anatomy, pathology, physiology, pharmacology, toxicology and surgery through the use of software, self-experimentation apparatus and the establishment of a body donation program for ethically sourced animal cadavers.

IAVA works closely with InterNICHE as a Partner organization.

More information: http://noanimaltesting.ir (site in Farsi)

Adapted from InterNICHE Newsletter December 9, 2016

NLD: NCad provides opinion on transition to non-animal research

Responding to the Dutch Minister for Agriculture, Martijn van Dam, who in March 2016 called for The Netherlands to become a world leader in innovations without laboratory animals by 2025, the National Committee for the protection of animals used for scientific purposes (NCad) published an opinion in December 2016.

Regarding regulatory research, the opinion states "The use of laboratory animals in regulatory safety testing of chemicals, food ingredients, pesticides and (veterinary) medicines can be phased out by 2025, whilst maintaining the existing safety level. The same applies to the use of laboratory animals for the release of biological products, such as vaccines. At this stage, regulatory pre-clinical research cannot be phased out at the same pace." Addressing fundamental research, the opinion calls for the development of a ten-year vision for each area of fundamental scientific research that will show the opportunities for reduction of animal research. It suggests that the transition in the field of applied and translational research may be brought about by focusing more heavily on innovations without laboratory animals. Finally, the opinion indicates a significant potential for reduction of animal experiments in education and training, although it considers a minimal use of laboratory animals in training professionals to remain necessary.

More information: http://bit.ly/2hZ69ed

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SUI: Foundation Animalfree Research celebrates 40th birthday

On November 16, 2016, Animalfree Research had invited donors, network partners and several of their project leaders to Zurich in order to celebrate its 40th anniversary. Founded as *"Fonds für versuchstierfreie Forschung"* FFVFF in 1976, the foundation has always relied exclusively on private donations. During the celebration, project leaders demonstrated and explained their work, and an accompanying poster exhibition informed about the history and future plans of Animalfree Research.

In order to reach more interested parties and ensure sustainability, the exhibition moved on to the Campus Irchel, University of Zurich, immediately afterwards for a month-long display. For 2017, the foundation aims for further opportunities at other Swiss academic institutions. The dates and locations will be published on the foundation's website http://www.animalfreeresearch.org.

> Stefanie Schindler Animalfree Research

SUI: Studies find scientific rigor in animal experiments lacking

Two studies published by Hanno Würbel and colleagues at the University of Berne question the scientific rigor of animal experiments performed in Switzerland.

In the first study (https://doi.org/10.1371/journal.pbio. 2000598) the scientists screened 1,277 approved applications for animal experiments in Switzerland as well as a random sample of 50 scientific publications resulting from these animal experiments for reporting of seven basic measures against bias (allocation concealment, blinding, randomization, sample size calculation, inclusion/exclusion criteria, primary outcome variable, and statistical analysis plan) and found that none of these criteria were mentioned in more than 20% of applications and none were reported in more than 35% of publications.

To investigate whether the criteria were just not reported or not applied, 2,000 animal researchers were asked in an online survey whether they applied these procedures during animal studies to reduce bias (https://doi.org/10.1371/journal. pone.0165999). High percentages of researchers stated that they did use these criteria and that they had reported them in their latest publications. However, when these statements were followed up, reporting rates were again below 20%.

These studies indicate that often neither ethical committees nor scientists nor reviewers nor journals appear prepared to take the responsibility to ensure that animal studies are designed and reported in accordance with best practices, such as recommended by the Experimental Design Assistant (https://www.nc3rs. org.uk/experimental-design-assistant-eda) and the ARRIVE guidelines (https://www.nc3rs.org.uk/arrive-guidelines), both developed by the NC3Rs.

The findings of the studies were reported among others by Swiss national newspapers.

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UK: LUSH Prize awarded

The 2016 LUSH Prize winners were announced on November 10, 2016. The international prize honors projects working towards ending animal testing. The winners, who were selected from 102 nominations, represent 20 projects from 11 countries. A total of £330,000 was awarded across the five categories.

This year the number of Young Researcher Awards was increased from 5 to 13, providing a £10,000 bursary per researcher to pursue their scientific goals without harming animals. Young Researcher Awards for scientists working in the Americas and Asia were presented at separate ceremonies in Vancouver and Seoul. The ceremony in London honored the winners of the categories Lobbying, Public Awareness, Science, and Training, as well as the Young Researchers from the rest of the world. Prior to the London ceremony the 2016 LUSH Prize International Conference themed "Regulating Chemical Safety – the future for animal use" was held at the Royal Society for the Arts.

The Lobbying Prize went to the 1R Institute of Promotion and Research for the Replacement of Animal Experimentation in Brazil and to People for Animals India. Vshine Animal Protection Association China won the Public Awareness Prize and ALTEX was commended by the judges in this category. Marcel Leist from the University of Konstanz, Germany and Daniele Zink and Lit-Hsin Loo from A*STAR, Singapore won the Science Prize. The Training Prize was split between the company Kirkstall and the Iranian Anti-Vivisection Association.

More information: http://lushprize.org/2016-prize/

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UK: Animal Replacement Centre of Excellence (The ARC) opened

DHT Patron and star of Downton Abbey, Peter Egan, has launched The Animal Replacement Centre of Excellence (The ARC), at Queen Mary University of London's Blizard Institute.

Through the DHT's investment of £1,000,000, Professor Mike Philpott and Dr Adrian Biddle will create a unique center of excellence. Using cutting-edge scientific research, The ARC will accelerate the development of human models for human disease and help reduce the number of animals currently used in cancer research.

The ARC aims to further develop the most robust and applicable non-animal research methods for human cancer, addressing the limitations of both poorly performing cell based approaches and animal models. The over-dependence on mouse models in particular has slowed progress in cancer research, and can provide misleading data. There is therefore a pressing need for human focused non-animal technologies that have demonstrable relevance to human cancer – The ARC aims to directly address this issue.

> Dr Hadwen Trust newsletter October 26, 2016

USA: EPA launches voluntary pilot program to reduce animal testing

On December 20, the U.S. Environmental Protection Agency launched a voluntary pilot program to evaluate the usefulness and acceptability of a mathematical tool that estimates the toxicological classification of a chemical, and published guidance on how pesticide companies can submit data for the program. This program is another step toward EPA's goal of reducing animal testing by adopting better testing methods, as described in the March 2016 Letter to Stakeholders issued by Office of Pesticide Programs Director Jack Housenger (http:// bit.ly/2hVDg4q).

The mathematical tool, known as the GHS Mixtures Equation, is used in the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Use of the GHS Mixtures Equation can reduce animal use for oral and inhalation toxicity studies of pesticide formulations.

To evaluate the GHS Mixtures Equation, EPA requests submission of acute oral and acute inhalation toxicity study data paired with mathematical calculations (GHS Mixtures Equation data) to support the evaluation of pesticide product formulations. EPA expects that the pilot will run for approximately six months but will begin data analysis sooner if enough data is received.

More information and instructions for submitting data: http://bit.ly/2iLhKAK

NICEATM News January 4, 2017