

News

AUS: Planned ban on cosmetic products tested on animals

Assistant Health Minister Ken Wyatt announced plans to bring Australia into line with the European Union and New Zealand by July 1, 2017, by banning the sale of cosmetic products and the use of cosmetic ingredients that have been tested on animals. Although animal testing is not currently performed for the production of cosmetics in Australia, there is no legislation banning companies from doing so. Cosmetic products manufactured in other countries may be sold in Australia independent of whether they or their ingredients were tested on animals. The ban would affect only new and not existing products.

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EU: REACH annexes amended – registrants to use alternative test methods

The REACH requirements for skin corrosion/irritation, serious eye damage/eye irritation, acute dermal toxicity and skin sensitization have changed, making non-animal testing the default requirement. ECHA reminded registrants of their obligations to consider and, where possible, use alternative methods.

The amended REACH annexes concerning skin and eye irritation and acute dermal toxicity were published in the *Official Journal of the European Union* and entered into force on June 20. In addition, the amendments for skin sensitization are expected in autumn 2016. In many cases, the information needed under REACH for the classification or risk assessment of a substance will now be obtained through non-animal methods.

Companies need to take the changed requirements into account when submitting information to ECHA. To pass the completeness check of registration dossiers, registrants need to give information according to the new legal requirements since June 21, 2016 when the new version of REACH-IT was launched (see below). For skin sensitization, the new requirements will be implemented in the completeness check in the autumn.

Registrants who have already submitted studies conducted in accordance with the previous requirements do not need to modify their registration dossiers immediately. However, when updating their dossier, they need to follow the new requirements. Those registrants who, for example, met the previous requirements with an *in vivo* study do not need to carry out additional *in vitro* studies. However, a justification for not submitting the *in vitro* study needs to be included at the time the dossier is updated.

To help companies, ECHA is updating its guidance on information requirements in the autumn. The Agency will also shortly update its advice on the use of OECD test guidelines related to skin and eye irritation. Step-by-step instructions for preparing dossiers with IUCLID 6 are available in a user manual. In addition, the IUCLID 6 Validation Assistant allows registrants to check their dossiers for completeness before submitting them to ECHA.

Adapted from ECHA/NA/16/20

EU: ECHA requires considerations for alternative methods to be included in testing proposals

Following a decision of the EU Ombudsman of September 11, 2015 (1606/2013/AN), ECHA has been separately requesting companies who propose tests involving vertebrate animals to show that they have fully considered alternative methods before concluding that a new animal test is necessary. Considerations submitted are published on the testing proposal consultations web page.

With the launch of the new version of REACH-IT, these considerations need to be documented in the registration dossier created with IUCLID 6 and will be subject to the completeness check that ECHA runs on each dossier it receives. This means that since June 21, a dossier with a proposal to test on vertebrate animals needs to have documented considerations of alternatives for each proposed vertebrate study to pass the completeness check.

IUCLID 6 contains a specific form to assist applicants in documenting their considerations. The details provided have to be meaningful and comprehensive.

All considerations for alternatives submitted in the registration dossier will be published under the *Information on Chemicals* section of ECHA's website, and therefore no confidential information should be included in the form. The information is linked to the third party consultation so that third parties can then take it into account when submitting scientifically valid information or studies that address the substance and the endpoint subject to the testing proposal.

The applicant's considerations and the third party information will be taken into account in ECHA's evaluation of whether the vertebrate animal testing is necessary.

Adapted from ECHA/NA/16/25

EU: Guide on avoiding new animal tests for REACH registration available

Cruelty Free International (CFI) and the European consultancy TSGE have published a guide on how to avoid animal testing for REACH 2018 registrations. Since the adoption of EU chemicals regulation REACH in 2006 there have been a number of important developments in alternative methods of testing chemicals without using animals. Several methods have been approved that can fully replace some animal tests, while there are new waiving options for others. In particular, there have been significant improvements to cell-based (*in vitro*) tests and computer (*in silico*) models.

How to avoid new animal tests in your 2018 REACH registration, produced in conjunction with TSGE Consulting, outlines the breakthroughs in alternatives and summarizes the changes to chemical regulation.

The simple guide is aimed at companies needing to register for REACH 2018, those assisting companies in their registrations, and anyone involved in commissioning new tests.

Full guide available at: <https://www.crueltyfreeinternational.org/REACHguide2018>

Adapted from
<https://www.crueltyfreeinternational.org>

EU: Study on fish embryo toxicity test published

ECHA has commissioned a study to analyze data on fish embryo toxicity (FET). It was compared with available data on standard acute fish toxicity (AFT), and parameters were set up to define the applicability domain and limitations of an FET test in comparison to AFT. The outcome gives a basis to understand how the FET test might be used in the regulatory context of REACH.

Full study: <http://www.echa.europa.eu/web/guest/publications/technical-scientific-reports>

ECHA weekly
May 25, 2016

EU: Presentations of ECHA Workshop available

The "Topical Scientific Workshop on New Approach Methodologies in Regulatory Science" on April 19-20, 2016 explored the potential regulatory benefits arising from fundamental change in scientific thinking.

Complex toxicological apical endpoints cannot be predicted by a single non-standard test. Instead, it is necessary to combine multiple lines of evidence (including 'omics' and high-throughput screening methods) to predict the hazardous property with tools to facilitate this integration of evidence.

Two motivating drivers for the workshop were:

- A better understanding of the underlying biology behind how chemicals cause adverse effects to human health; and
- New tools and techniques that provide a huge amount of data to be used in solving regulatory issues.

The workshop drew inspiration from the EU research programme SEURAT-1 and the US Tox21 initiative, and also took into account general progress from the scientific field.

Presentations are posted at: <http://bit.ly/1NZKuL1>

Adapted from <http://bit.ly/1NZKuL1>

EU: EPAA 3Rs Science Prize open for submissions

The European Partnership for Alternative Approaches to Animal Testing (EPAA) has launched its call to apply for the 2016 3Rs Science Prize. This year, the EPAA will grant a Prize for already achieved research, or a project already at the completion stage with outstanding results. The EPAA 3Rs



Science Prize is granted every other year to a scientist whose contribution to 3Rs is found to be outstanding. Its purpose is to promote such positive contributions from industry or academia and to encourage more scientists in the future to focus their research to the 3Rs goals. Scientists working on methods for safety and/or quality testing and applying the 3Rs (re-placement, reduction or refinement of animal testing) to those methods may apply for the prize. An EPAA jury made of 6 representatives (2 from industry, 2 from European Commission and 2 from the EPAA Mirror Group) evaluates the submissions and provides the EPAA Steering Committee with a detailed recommendation. Based on this recommendation, the SC should then endorse the winner, and grant a €10,000 prize.

The prize grant will be provided to the research institution of the successful candidate to be announced at the EPAA Annual conference on December 5, 2016. The awardee will also get the opportunity to give a presentation of his/her work in front of the EPAA annual conference participants, gathering regulators, industry stakeholders, academia and civil society.

Submission deadline: September 23, 2016
More information: <http://bit.ly/29kseja>

GER: Call for tenders for the Felix Wankel Animal-Welfare-Research-Award 2017

The Felix Wankel Animal-Welfare-Research-Award is usually bestowed every two years by the Faculty of Veterinary Medicine of the Ludwig-Maximilians-University Munich for outstanding experimental and innovative scientific papers aiming at or resulting in the replacement or reduction of animal testing, the general fostering of the idea of animal protection, ensuring the health and the appropriate housing of laboratory animals, pets and livestock, or supporting core research for the purpose of enhancing animal protection.

The Award is endowed with up to €30,000 and may be divided among several prize winners. Utilization of the prize money is not subject to any conditions. Those entitled to nominate are scientists as well as members of scientific institutions, expert societies, authorities, etc., or representatives of the scientific media. The nominees can be persons or groups involved in research in Germany or abroad. The papers should be recent and contain the results of original research. They must be available in print. Papers which have already received an animal protection award will normally not be considered. Self-nomination is not permitted.

Triplicate copies of the paper must accompany the letter of nomination. In addition, a CD ROM containing electronic files (PDF format) of a curriculum vitae, a bibliography and a

summary not exceeding two pages in German and/or English shall be submitted, reflecting the state of the art, the research approach and the results. One copy of the papers submitted will be placed on permanent file with the Board of Trustees.

The award decision is made by the Board of Trustees of the Felix Wankel Animal-Welfare-Research-Award, ousting the jurisdiction of the courts.

Submission deadline: September 30, 2016
More information: <http://www.felix-wankel-forschungspreis.de>

W&ST Wissenschaft statt Tierversuche

Wissenschaftlicher Kongress am Samstag, 15. Oktober 2016 in Köln

GER: Science instead of Animal Experiments Congress

The use of animals in biomedical research and testing is still largely regarded as the norm. However, this view is increasingly coming under scrutiny in light of current scientific knowledge. In parallel, significant progress has been made in the field of non-animal research methods. In addition to ethical concerns, animal studies are also the subject of criticism from within the scientific community itself. Awareness is growing that new methodologies are required to gain insight into important questions of human health and disease. Animal experimentation has not provided the hoped-for and much needed answers to these vital questions.

The event is aimed at researchers, physicians, veterinarians, students, officials, politicians and the general public. The program will consist of two parts:

1. Questioning the validity of animal experiments in relation to human medicine
2. The development and use of human-based research methods as a replacement for animal studies

The presentations will be in English or in German, with no simultaneous translation. A good understanding of both languages by all participants is therefore recommended.

Saturday, October 15, 2016, 10:00-18:00
Cologne, Germany
<http://www.wist-kongress.de/>

GER: Hamburg offers 3Rs research prize

Hamburg's authority for health and consumer protection has announced the first Hamburg Research Prize to support the development of alternative and complimentary methods to animal experiments (*1. Hamburger Forschungspreis zur Förderung der Entwicklung von Ersatz- und Ergänzungsmethoden zum Tierversuch*).

Animals are used to answer numerous scientific questions. Animal experiments performed to address a variety of scientific questions cause animals pain, distress and damage. However, as anchored in the German constitution, man has a responsibility to animals as fellow creatures and is obliged to protect their life and well-being. According to the Animal Protection Act, animal experiments may only be performed if no other methods are available to answer the question. Despite the progress in the area of alternative methods there is much to be done in the development and validation of alternative methods.

To expedite the development of alternative methods to animal experiments in all areas in which animal experiments are performed, the authority for health and consumer protection and the authority for science, research and equality announce a research prize totaling €20,000. The prize will be awarded for exceptional, innovative scientific projects that contribute to the replacement or reduction of animal experiments. Refinement projects may also be considered.

Application deadline: September 30, 2016

More information: <http://www.hamburg.de/tierschutz-tiergesundheits/6054484/forschungspreis/>

INT: HIS/HSUS to fund publication of roadmaps to extend Tox21 to biosciences

Grants are being offered through Humane Society International and The Humane Society of the United States to support the preparation and journal publication of independent, in-depth reviews of research progress in key human disease areas.

The aim of this grant program is to support strategic scientific dialogue regarding the potential of extending the U.S. National Research Council vision of 21st century toxicology to the wider field of biosciences. To this end, each review article will need to 1) critically evaluate the state of the science, including mechanistic understanding of the pathophysiological pathways/networks underlying the disease in humans, the human relevance, translational success and limitations associated with available research models, and 2) provide a detailed proposal for optimizing the use of modern, human

biology-based tools and approaches (*in vitro*, *in silico*, bio-engineering, etc.) into the research paradigm to potentially improve translational success in future.

Applicants with a scientific PhD (or equivalent) and current or recent research and publication experience in an area of human disease, are invited to tender for one of these grants. Successful applicants will receive a stipend based on market equivalence, up to a maximum of £5,000, conditional upon signing an Independent Contractor/Consultant Agreement with HSI/HSUS. In addition to publication of the review, applicants will be required to participate in at least one conference/workshop, to be agreed on with HSI/HSUS. The aim of this follow-up event will be to facilitate open discussion of animal models and further disseminate this research.

Deadline for applications:

July 31, 2016 at midnight EDT.

More information: <http://www.hsi.org/rfp>

INT: Deadline for AOP Awards extended

The PETA International Science Consortium Ltd. (PISC) is sponsoring a competition to encourage contributions to a collaborative resource for adverse outcome pathway (AOP) development. The AOP Wiki (https://aopwiki.org/wiki/index.php/Main_Page) was created by the European Commission's Joint Research Centre, the U.S. Environmental Protection Agency, and the Organisation for Economic Co-operation and Development (OECD) to provide an interactive and virtual platform for AOP development and to promote international consensus on the developed AOPs. To encourage new contributors to add to existing entries in the AOP Wiki using available data, PISC is offering cash awards to the best contributions to the AOP Wiki by new users.

The competition is open only to people who made no contributions to the AOP Wiki before September 15, 2015. Entries will be judged by the OECD's Extended Advisory Group on Molecular Screening and Toxicogenomics. Prospective competitors must register with PISC.

Competition deadline: extended to October 3, 2016

More information: <http://www.piscld.org.uk/aop-prize/>

Adapted from NICEATM News
June 2, 2016



SUI: News from ALTEX

Heike Behrendorf-Nicol is the winner of this year's ALTEX Prize for the best article published in 2015. The paper, titled "'BINACLE' Assay for *In Vitro* Detection of Active Tetanus Neurotoxin in Toxoids" co-authored with Karin Weisser and Beate Krämer was published in ALTEX 2/15, <http://dx.doi.org/10.14573/altex.1412181>.

The Prize consists of a CHF 2,000 personal prize, this year again generously sponsored by the Doerenkamp Zbinden Foundation, and will be presented at the EUSAAT 2016 Congress in Linz, Austria, by Mardas Daneshian, President of the Society ALTEX Edition. The members of the Board, Editorial Board and Editorial Office elected the winner of the annual prize out of all main articles published in 2015; articles including members of the ALTEX Board and Editorial Office as first or last authors were excluded.

The Thomson Reuters Journal Citation Report 2015 was released in June. ALTEX' impact factor rose to 5.824. The five-year impact factor is now 5.205. ALTEX is thrilled about this recognition of 3Rs papers in the scientific community.

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UK: From dogs to 3D tissue models: the 2015 3Rs Prize

Three pieces of outstanding published research with 3Rs impacts have been given awards in this year's 3Rs Prize competition, run by the NC3Rs, and sponsored by GlaxoSmithKline (GSK). The Prize ceremony took place on February 29, 2016. The 3Rs Prize is part of NC3Rs strategy to recognize excellence in science which minimizes animal use or improves animal welfare.

Two papers were declared joint winners of the 2015 Prize. The first by Lancaster et al. describes a 3D model of the embryonic human brain created from stem cells (<http://dx.doi.org/10.1038/nature12517>). These so-called 'cerebral organoids' represent a major scientific breakthrough because for the first time the complexity and structure of the developing brain has been replicated *in vitro*. This has significant implications not only for studying neurological diseases but also for replacing some animal studies.

The second paper awarded the top prize focuses on the application of a framework to assess the welfare of the laboratory dog based on their behavior, health and psychological well-being (<http://dx.doi.org/10.1016/j.vascn.2014.12.007>). The framework described by Hall et al. was used to validate a refined procedure for administering substances to dogs during the testing of new drugs. Gavage – the use of a thin tube temporarily inserted into the stomach via the mouth – is a common procedure for delivering drugs and this work has

the potential to minimize stress in thousands of dogs used in testing worldwide.

A highly commended award was also made for a paper describing the development of 'personalized' organoids of colorectal cancer derived from the patients' own tissue (<http://dx.doi.org/10.1016/j.cell.2015.03.053>). The collection of organoids represents the main mutations causing cancer and therefore could be used to test drugs and identify drug combinations suitable for specific patients. Such studies are traditionally carried out in mice where samples of human tumors are implanted under the skin and the ability of various treatments to inhibit the growth and spread of the tumor are studied.

Adapted from NC3Rs News
March 2016

UK: LUSH Prize nominations open

The fifth LUSH Prize opened for nominations on April 25, 2016. There will again be six prize categories, i.e., Science, Young Researchers, Training, Public Awareness, Lobbying, and Black Box. A winner of the Black Box category would win the whole £250,000 prize money. If no Black Box winner is found, £50,000 is awarded in each of the other five categories.

The Lush Prize works specifically to fund initiatives to end animal testing in the area of toxicology and only supports complete replacement of animal tests. The global prize fund is open to self-nominations and nominations from all over the world.

Further information: <http://www.lushprize.org/awards/>
Deadline for nominations: July 24, 2016

UK: Improving compliance with the ARRIVE guidelines

We are carrying out a randomized controlled study – IICARus (Intervention to Improve Compliance with the ARRIVE guidelines) – to assess whether mandating the completion of an ARRIVE checklist improves full compliance with the ARRIVE guidelines. Manuscripts, limited to *in vivo* studies, will be scored by two independent reviewers against the operationalized ARRIVE checklist, blinded both to intervention status and to the scores from the other reviewer.

Discrepancies will be resolved by a third reviewer who will be blinded to the identity, and unblinded to the scores, of the previous reviewers.

It is a big project and we would like to get you involved in assessing manuscripts! There is an online training module accompanied by a resource which is a prerequisite for becoming a reviewer for this study.

To register and start the training for this study please sign up: <https://ecrf1.clinicaltrials.ed.ac.uk/iicar-us/Account/Register>

Please register to access to the training module, accompanied by a resource, a prerequisite for reviewing for this study.

We would really appreciate your collaboration and support with this endeavor! The resulting papers will be published in the name of the IICARus collaborators, and all individuals scoring manuscripts will be listed as collaborators (which means it comes up under your name in PubMed). We expect these will be interesting and impactful papers. We plan for the listing of contributions to follow the format for the AVERT trial (<http://www.ncbi.nlm.nih.gov/pubmed/25892679>).

<https://ecrf1.clinicaltrials.ed.ac.uk/iicar-us/>

USA: 2017 Science-based Refinement Awards

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 2017 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. Studies may, for example, examine:

- how physiological and behavioral stress responses to common husbandry (e.g., capture) and traditional treatment procedures (e.g., gavage, injection, blood collection) can be reduced or eliminated (e.g., by training the subjects to cooperate rather than resist);
- whether animals caged at different tier levels show different physiological and behavioral stress responses when being approached by personnel, and how these responses can be minimized or avoided;
- whether the presence of a compatible companion buffers physiological and behavioral stress responses to experimental situations (e.g., enforced restraint);
- whether animals kept in legally minimum-sized cages benefit from a moderate increase in space that is (a) empty versus (b) structured in species-appropriate ways (e.g., shelter, visual blind, perch, platform, PVC tube).

Any studies to be undertaken must be non-invasive, with the possible exception of obtaining blood for biochemical meas-

urements (animals that have been trained to cooperate during venipuncture should be used, if possible). Objective measures might include behavior, coat appearance, body weight, analysis of feces, urine, or blood as described above. Preference will be given to studies that have broad applicability.

Each award will be for \$6,000. There are no F&As allowed on this award.

These awards are intended for veterinarians and laboratory and animal technicians.

Deadline for submissions: November 18, 2016

More information:

<http://caat.jhsph.edu/programs/awards/AWE/2017/index.html>

USA: TSCA reform bill signed into law

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law by US President Barack Obama on June 22, 2016. This bill modernizes the Toxic Substances Control Act (TSCA) of 1976. Within the first year, the EPA must now establish processes for prioritization, risk evaluation and “resetting” the inventory of chemicals in commerce. According to an EPA press release, improvements included in the new law are:

- Mandatory requirement for EPA to evaluate existing chemicals with clear and enforceable deadlines;
- New risk-based safety standard;
- Increased public transparency for chemical information; and
- Consistent source of funding for EPA to carry out the responsibilities under the new law.

The new law also includes language that requires EPA to develop a plan to promote the use of alternative methods that reduce, refine, or replace vertebrate animal testing and include in that plan a list of acceptable alternative methods.

Full text of the new law:

<http://1.usa.gov/29bBbz0>

Implementation plan:

<http://1.usa.gov/294nm11>

Overview of provisions of the new law:

<http://1.usa.gov/28OH93w>

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