# News

## EU: ECHA gives out registration data to support development of non-test methods

The European Chemical Industry Council (Cefic) has been given access to certain data from ECHA's chemicals database to develop a new tool for predicting toxicity of chemicals. The new software, called AMBIT, for cheminformatic data management is developed under an industry-led project. It consists of a database of more than 450,000 chemical structures and functional modules allowing the data to be searched and mined. The aim of the tool is to avoid unnecessary testing on animals when filling information gaps on chemicals.

ECHA supports this industry initiative by giving Cefic access to carefully-selected parts of the non-confidential registration data, to protect the rights of the data owners.

The Agency is keen to see data on chemicals being used to enhance their safe use, promote innovation and avoid unnecessary testing on animals. However, while the chemicals database is a very good resource for data, parts of the information are protected by rights belonging to third parties, for example intellectual property rights. Companies have invested heavily in generating the data and there are different laws in place to safeguard its reuse. This is also mentioned in the legal notice on ECHA's website.

ECHA is currently analyzing how to make the data more readily available to a wider audience (e.g. academia, companies, researchers, regulators) in a way that respects the ownership of companies. In addition to Cefic's AMBIT project, ECHA has provided similar sets of data to the OECD QSAR Toolbox.

ECHA has the legal obligation to make data submitted to it through REACH registrations and CLP notifications publicly available. This is done through the *Information on chemicals* section of the website. This is a unique source of information on up to 120,000 chemicals manufactured and imported in Europe. It covers their hazardous properties, classification and labelling, and information on how to use them safely.

ECHA/NI/16/07

## EU: Full replacement of *in vivo* tests possible for REACH

ECHA will publish advice on using the new OECD test guidelines related to serious eye damage/eye irritation and skin corrosion/irritation in 2016. For skin corrosion/irritation, the new *in vitro* tests can, in many cases, fully replace *in vivo* studies when used either alone or in combination. For serious eye damage/eye irritation, combinations of several alternative test methods may be used to replace *in vivo* testing.

In mid-2016, the Agency plans to publish an update to the guidance on information requirements (Endpoint specific guidance, (Chapter R.7a)) to reflect both the scientific changes and the recent regulatory amendments in the REACH annexes. The updates concern the data requirements for skin corrosion/irritation, serious eye damage/eye irritation, skin sensitization and acute toxicity.

For skin sensitization, there will be advice in using newly developed non-animal testing methods within a weight of evidence approach, which may be used to avoid *in vivo* testing. For acute toxicity, there will also be advice on using a weight of evidence approach, which can lead to avoidance of certain *in vivo* tests.

Additional information for registrants is published in the Practical guide: How to avoid unnecessary animal testing, http://echa.europa.eu/documents/10162/13655/pg_avoid_animal_testing_en.pdf.

Adapted from ECHA newsletter
February 18, 2016

## EU: Launch of EU-ToxRisk: A large-scale European *in vitro* toxicology project

EU-ToxRisk, the "integrated European 'flagship' program driving mechanism-based toxicity testing and risk assessment for the 21st century," was officially launched in January 2016 with an inaugural event in Hotel Zuiderduin in Egmond aan Zee, The Netherlands. Over 100 scientists representing academic and industrial institutions as well as regulatory authorities attended the kick-off meeting from January 13 to 15 in the Lamoraalzaal, which is shaped like the inside of a ship's hall, lending an appropriate metaphor for this project.

EU-ToxRisk intends to integrate advances in *in vitro* and *in silico* toxicology, read-across methods, adverse outcome pathways, i.e., mechanism-based toxicity testing, and risk assessment according to Tox21c principles. Marcel Leist (University of Konstanz, project partner) stated that EU-ToxRisk's goal is to "develop a new way to do risk assessment" and Bennard van Ravenzwaay (BASF, project partner) pointed out during his inaugural lecture that "this project is rather about regulatory risk assessment than about methods."

The focus of this six-year project lies on repeated-dose systemic toxicity testing involving liver, kidney, lung, and the nervous system, as well as on developmental and reproductive toxicity. Special effort will be paid to the implementation of chemical read-across, biological read-across procedures incorporating mechanistic and toxicokinetic knowledge, as well as hazard and risk assessment strategies. Due to the potential of chemical and biological read-across approaches and the importance of good-practice guidelines to this field, EU-ToxRisk's first workshop on February 26 in Brussels presented the new "Good Read-Across Practice guidance" and other relevant initiatives to stakeholders.

EU-ToxRisk coordinator Bob van de Water from the University of Leiden introduced the mission, "The development of a quantitative adverse outcome pathway (qAOP) concept for regulatory purposes integrating relevant *in vitro* and *in silico* technologies required for the assessment of chemical safety in humans." The concept of EU-ToxRisk was commented by Magdalini Sachana (OECD), an external advisor of the project with the words, "I was delighted to see that Adverse Outcome Pathways (AOPs) and Integrated Approaches to Testing and Assessment (IATA) play a central role in almost all the work packages of the project. I look forward to receiving more information and outputs from the project."

EU-ToxRisk already works on 17 case studies, and the consortium partners will start first on the basis of data-rich pharmaceutical compounds with the evaluation of the predictivity of a battery of assays. Subsequent case studies will be established for less characterized new classes of compounds. "The case studies with selected compounds will remain focused on adverse human consequences, i.e., provide relevant concentration-response models and tipping points of homeostasis in order to predict safe exposure levels," said Carl Westmoreland (Unilever – project partner). Derek Night (ECHA) emphasized "the importance of building toxicokinetics and toxicodynamics within EU-ToxRisk for weight of evidence approaches in risk assessment" with regard to the focus of the case studies. Thomas Steger-Hartmann from Bayer HealthCare commented as an external advisor of the project, "The well-organized and conducted kickoff meeting prepared the stage for an ambitious project that has the potential to change existing safety assessment paradigms. The case studies form the backbone of the project plan. A big part of the success of the project will depend on the thoughtful selection of test compounds, assay systems, and benchmark data for evaluation."

Russell Thomas from U.S. EPA (external advisor of EU-ToxRisk) stated that he "was impressed with the enthusiasm of the scientists involved in the project and the willingness to move beyond basic research and to apply their science to practical but important questions facing society in testing chemicals for human safety. There appear to be multiple points of intersection between the EU-ToxRisk project and the research being undertaken by the U.S. EPA in the National Center for Computational Toxicology. Collaboration at these points of intersection would benefit both organizations and allow us to achieve much more together than in isolation. I look forward to working with and advising the EU-ToxRisk project. It is poised to have a significant impact on the way we evaluate chemicals for human safety."

The lecture series given during the kick-off meeting of EU-ToxRisk mirrored the interdisciplinary character of the project and also the awareness of the partners of the pitfalls due to several aspects related to interdisciplinary approaches and conceptual works. For instance, Florian Caiment (University of Maastricht, project partner) on "The limitations of microarray technologies for transcriptomics and highlighting the benefits of RNA sequencing." Thomas Hartung (Johns Hopkins University, project partner) talked about "Challenges in computational toxicology" and Marcel Leist (University of Konstanz, project partner) spoke on "Model systems: Are they fit for purpose and what purpose do they fit?"

The spirit of all participants of the 14 work packages during the kick-off meeting was remarkably enthusiastic and optimistic. The positive start was helped by extensive preparations by the scientific steering team and the coordinator of the project already in 2015 in order to optimize and refine information flow and work flow of the project. Due to the latter, a remarkable geniality between the scientists was notable, which is unusual at the kick-off meeting of such large-scale project.

Mardas Daneshian
Steinbeis CAAT-Europe,
project partner

## GER: BMBF expands support program for alternatives to animal experiments

The Federal Ministry for Education and Research (BMBF) states that it aims to secure and strengthen Germany's leading position in the area of alternative methods to animal experiments. Its rules for the support of research and development projects in the area of alternative methods, last published in 2011, were updated in December 2015.

The BMBF will continue to support projects aiming to replace, refine or reduce animal experiments (module I) and will additionally support concepts for the dissemination of alter-

native methods, e.g. training courses, as well as strategies for the implementation of alternative methods, and accompanying studies, workshops, etc. (module II). In both modules emphasis is placed on the prompt and comprehensive harnessing of 3R potentials. Successful projects may be given the option of a two year extension. German projects within international collaborations can be supported under certain conditions. Individual or collaborative projects may be submitted by universities, research institutes or small or medium enterprises located in Germany.

Project proposals may be submitted via the internet portal https://www.submission-alternativmethoden-zum-tierversuch.de/ start by March 15 every year.

Adapted from BMBF Newsletter January 4, 2016

## GER: Baden-Württemberg calls for applications for 3Rs research funding and prize

The Ministry of Rural Affairs and Consumer Protection of Baden-Württemberg is accepting applications for research funding. A total of €400,000 is available. Suggestions for the 3Rs prize for exceptional contributions to reducing or refining animal experiments in research or education, which carries prize money of €25,000, can also be made.

Eligible research projects aim to develop alternatives to animal experiments or to reduce pain and distress of animal experiments in research and education. They must be performed in Baden-Württemberg or in cooperation with institutions located in Baden-Württemberg.

The research prize for exceptional contributions to replacing, reducing or refining animal experiments in research or education may be awarded for work performed in any state of Germany.

Deadline: April 30, 2016
More information: bit.ly/1TKJuS4

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## GER: Hesse calls for applications for Animal Protection Research Prize

The Minister for the Environment of Hesse announced the 2016 Animal Protection Research Prize, which is awarded for exceptional scientific work that points the way toward the avoidance or reduction of animal experiments in research, education, or in the production of biomedical products such as vaccines and antibodies. Contributions that lead to a reduction in pain or distress are also considered. Award-worthy contributions establish new methodologies or continue the development of methodologies towards practical application. Persons or groups that are scientifically active in Hesse or companies or institutes located in Hesse may apply or suggest prize winners. The prize money is €14,000.

Application deadline: July 1, 2016
Further information: www.tierschutz.hessen.de

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## GER: Legal opinion finds Germany in violation of Directive 2010/63/EU

On March 7, 2016 the parliamentary party *Bündnis 90/Die Grünen* published a legal opinion authored by Dr Christoph Maisack, indicating that the German Animal Protection Law* violates Directive 2010/63/EU on the protection of animals used for scientific purposes in 18 counts. Some examples given are:

- Under German law, animal experiments for educational purposes need only be notified and can be begun 20 days after notification unless rejected by the authority, while the EU Directive requires such experiments to be subject to approval by the authority.
- The EU Directive requires an independent harm-benefit analysis of every proposal by the authority before authorization of an animal experiment. The German Law requires only a plausibility control of the applicant's harm-benefit analysis and arguments for the indispensability of the experiment.
- Regarding severe animal experiments, the EU demands that these are generally forbidden or limited to exceptional circumstances and may only be authorized provisionally in specific cases. Such a limitation is absent in the German Animal Protection Law.

The animal protection organizations *Ärzte gegen Tierversuche*, *Bund gegen Missbrauch der Tiere* and *Menschen für Tierrechte* among others have responded to the legal opinion by again calling for a comprehensive revision of the German Animal Protection Law.

Full legal opinion: https://www.aerzte-gegen-tierversuche.de/images/stories/temp/maisackgutachtentierversuche.pdf

*Drittes Gesetz zur Änderung des Tierschutzgesetzes of July 4, 2013 (BGBl. I S. 2182-2196) and Tierschutz-Versuchstierverordnung (TierSchVersV) of August 1, 2013 (BGBl. I S. 3125-3145)

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## INDIA: MGDC receives UGC support for continuation

The Doerenkamp-Zbinden Foundation-sponsored Mahatma Gandhi-Doerenkamp Center (MGDC) for Alternatives to the Use of Animals in Life Science Education, with the Gandhi-Gruber-Doerenkamp Chair for Life Science Education and In Vitro Toxicology, established in July 2009 at Bharathidasan University, Tiruchirappalli in India, with People for Animals (P*f*A), Chennai, as a supporting partner, has been working tirelessly in the cause of animals in India, particularly in the domains of education and training, chemical risk assessment, drug discovery and cosmetics testing. Tenured for five years, the Center / Chair was scheduled to be wrapped up in June 2014, since the Foundation was not in a position to support its continuation. However, the incumbent Chair was able to self-generate small funds such that the activities could be continued until March 2016. In the meantime, in order to sustain the activities of the Center after this date and encouraged by the Foundation, P*f*A, and the Vice-Chancellor of the University, the incumbent Chair put enormous effort into mobilizing financial support from an Indian Government Funding Agency. Now, it is heartening that the University Grants Commission (UGC), New Delhi, has sanctioned an amount of INR Five Crores (INR 50 million) under the "Center with Potential for Excellence in Particular Areas (CPEPA)" scheme for a "National Center for Alternatives to Animal Experiments (NCAAE)." This Center will essentially be a continuation of the MGDC, with much more emphasis on courses as well as research on alternatives, but without the Chair. The following shall be the objectives of NCAAE, India:

- To establish a national repository and reference point of literature on animal alternatives and to keep it up to date; to provide access to the literature to the stake-holders.
- To establish a repository of digital and simulation alternatives for dissections and animal experiments, introduce newer digital alternatives, to update them regularly and train the stake-holders in these alternatives.
- To establish the facilities for and provide training in *in vitro* alternatives; to establish a co-culture facility and a 3D culture facility; to bring up new technologies / variants of existing technologies so as for India to be at least self-reliant in respect of products and processes; to facilitate scientists / researchers with these facilities and to apply these technologies in research and risk assessment; to provide training to stake-holders.
- To provide an *in silico* alternatives facility and training; to introduce newer *in silico* tools and newer applications for existing tools; to facilitate scientists / researchers with these tools; to provide training.
- To offer academic programs on alternatives
- To support networking of individuals, institutes and labs engaged in contributing to alternatives; to conduct seminars, symposia, conferences and national and international congresses on alternatives.

DZF, P*f*A and the Founder-Chair are very proud that this facility, which will blossom and prosper into a force to be reckoned with, was seeded by them. Thus, DZF and P*f*A will have a permanent and coveted place in the history of the alternatives movement in India.

Mohammad A. Akbarsha
Mahatma Gandhi-Doerenkamp Center (MGDC) for Alternatives to the Use of Animals in Life Science Education & Gandhi-Gruber-Doerenkamp Chair for Life Science Education and In Vitro Toxicology, Bharathidasan University, Tiruchirappalli, India

## INT: World Animal Net publishes Model Animal Welfare Act

World Animal Net has published its Model Animal Welfare Act, which can be downloaded (http://bit.ly/1M4kaEh) or accessed as a web version (http://worldanimal.net/our-programs/model-law-project).

The Model Animal Welfare Act can be used as a guide and information source for any countries seeking to introduce or improve their animal welfare legislation. To assist in this task, in addition to presenting the text of the Model Act, other helpful aspects have been included such as underlying rationale (including a brief overview of the current animal welfare policy environment) and full explanatory notes which incorporate: reasons for the suggested approaches selected, and alternative options; recommendations for policy and enforcement mechanisms; advice on potential pitfalls; and guidance on the content needed in implementing regulations.

The Model Animal Welfare Act covers all aspects of animal welfare. In addition to guiding principles and rules ("core obligations") – which are provided to ensure a coherent and consistent approach to animal welfare across all sectors – the following specific categories of animal use/issues are included:

- Companion animals (pets) – including stray dog and cat management;
- Animals kept for farming purposes – including fish farming – as well as animal transport and killing/slaughter;
- Animals used for experimentation – including science, research and testing;
- Wildlife – including "pest" control, and animals in zoos/aquaria;
- Animals used for work; and
- Animals used for sports, leisure or entertainment.

It is recognized that this Model Animal Welfare Act will need to

be adapted to take account of each country's national situation and specific animal welfare concerns. However, with this new resource countries will have the opportunity to design modern, comprehensive animal welfare legislation on a very high level.
World Animal Net is an internationally recognized NGO with offices in the United States, The Netherlands, the United Kingdom, and South Africa. WAN has a network of over 3,000 affiliate animal welfare societies in more than 100 countries, and consultative status at the United Nations.

Adapted from
World Animal Net
February 8, 2016

## NL: Spanish translation of humane endpoints website released

The 3Rs-Centre Utrecht Life Sciences has released the Spanish translation of the Humane Endpoints website. With the Spanish translation included, the website is available in four languages. The fifth and last language, German, will be added later in 2016. The Humane Endpoints website (http://www.humane-endpoints.info) informs how to recognize humane endpoints in laboratory animals. This helps to prevent further distress in the animals by removing the animals from the experiment (e.g. euthanizing the animals) or by applying analgesia. The website contributes to refinement: the prevention of unnecessary distress in laboratory animals.

The website is already successfully used in several laboratory animal science courses worldwide. It has 1200 unique visitors a month and over 400 registered users for the secured section of the website. With the addition of the Spanish translation, the website can be consulted by more people worldwide. Later this year the website will be extended with a German translation and information on humane endpoints in fish.

The Humane Endpoints website is, together with the Interspecies Database (http://www.interspeciesinfo.com), part of the 3Rs database program of the 3Rs-Centre Utrecht Life Sciences (ULS).

3Rs-Centre ULS Newsletter
January 25, 2016

## NL: In memory of Frauke Ohl

On 28 January 2016 we were shocked to be informed that Frauke Ohl passed away at the age of 50. With still many ideals to pursue, she was halted in her tracks by her battle with cancer, a struggle she could not overcome. Her passing is too early and a great loss for many of us.

Professor Frauke Ohl, a German-born biologist was Professor of Animal Welfare and Laboratory Animal Science at the faculty of Veterinary Medicine at Utrecht University since 2004. There she chaired the Department of Animals in Science and Society since 2006. In the Netherlands, she also served as the President of the Council on Animal Affairs, member of the National Advisory Committee for Animal Experiments Policy, the Covenant for Unanesthetised Ritual Slaughter Committee and President of the Ministry of Economic Affairs' Scientific Advisory Committee.

Internationally, Frauke was active as a member of the Board of Trustees of the Universities Federation for Animal Welfare, the Federation of Veterinarians of Europe working group "European veterinary education in animal welfare, science, ethics and law", member of the CAAT-Europe Board and an associate member of the European College of Animal Welfare and Behavioural Medicine. However, a simple summation of her official positions does not do her justice. She was so much more.

To people knowing her and working with her she was – and remains – an example. Her passion, vision and unceasing efforts for animal welfare, animal experiment studies and the 3Rs, and the sustainable and peaceful cooperation between humans and animals gave direction to her life until the very last moment.

Frauke was always conscious of the great importance of education, and always enthusiastically supported education at her

faculty, at national and international levels. The development of, and participation in, education on animal experiment studies, animal welfare and animal behaviour always came naturally to her.

Frauke was always able to find a balance between research, education and social activism, as witnessed by her large number of academic publications, the organisation of national and international conferences, and her excellent administrative work.

With Frauke Ohl, we have lost a person who worked tirelessly to make a better world for humans and for animals. Her leadership, inspiration and friendship will be sorely missed. We are grateful that we have known her and worked with her.

Jan van der Valk, PhD
Coordinator 3Rs-Centre Utrecht
Life Sciences
Dept. Animals in Science and Society
Fac. Veterinary Medicine
Utrecht University
The Netherlands
Phone +31 30 253 2163 / 2186
e-mail: j.vandervalk@uu.nl

## SUI: *Tier im Recht* turns 20 and confers first TIR Animal Law Award

The foundation *Stiftung für das Tier im Recht* (TIR) celebrated its 20th birthday on March 15, 2016. At the celebratory function the first „TIR Animal Law Award" for exceptional contributions to animal protection law was conferred to the Center for Animal Law Studies (CALS) at the Lewis & Clark Law School in Portland (Oregon/USA).

Since 1996 TIR has worked to improve the legal protection of animals. TIR states that it is the largest animal protection organization in Europe specialized on the legal aspects of the human-animal relationship. It has made sustainable contributions to animal protection and established itself as a competence center for animals in law, ethics and society.

The TIR Animal Law Award honors persons or institutes for exceptional contributions to national or international animal protection law. The first award was bestowed on the Center for Animal Law Studies (CALS), which is a hub for the education and training of animal protection lawyers. It offers students and practitioners almost unlimited opportunities to learn animal law and its work is well recognized internationally. CALS is a leader and international model for animal protection law education. The prize was accepted by Prof. Pamela D. Frasch, foundress and CEO of CALS.

Stiftung für das Tier im Recht (TIR)
Press release
March 15, 2016

## UK: Launch of NC3Rs-funded welfare assessment resource

A new e-learning resource (http://cbctraining.ncl.ac.uk/eM-EU5/story.html) focusing on the assessment of laboratory animal welfare has been launched to help researchers and animal care staff to identify signs of good and poor welfare in research animals.

Created by Professor Paul Flecknell and his team at Newcastle University, with funding from the NC3Rs, it is the second scenario-based training module to be added to the FLAIR e-learning site. Recipients of an NC3Rs Infrastructure for Impact award in 2013, the group from Newcastle are developing a range of web-based tutorials on best practice in the refinement of animal experiments.

Featuring videos, annotated images and questionnaires, the module places the user in situations they may encounter in the laboratory, in order to improve and to test their understanding of how to recognize and prevent pain, suffering and distress in research animals. The realistic scenarios currently focus on rodents; however there is material on other commonly used species, such as zebrafish and rabbits. Information on severity classification and humane endpoints is also included.

This free resource can be used as a basic introduction to the topic, a refresher, or for more specific training necessary for continued professional development. It has been specifically designed to meet the learning objectives of EU Module "Recognition and prevention of pain, suffering and distress in laboratory animals". The UK accrediting bodies (Society of Biology, Scottish Accreditation Board and Universities' Training Group) support the use of the resource in accredited training courses for personal license holders.

The first NC3Rs-funded e-learning module, on laboratory animal anesthesia for minor procedures, can be accessed at http://cbctraining.ncl.ac.uk/eM-EU20/story.html.
Versions of both modules that permit tracking of user completion are available at https://flairelearning.com/

NC3Rs News
January 29, 2016

## USA: FDA no longer recommends Draize test for topical drug evaluation

The U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) published guidance on "Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route. Guidance for Industry and Review Staff" in October 2015.

The guidance states (for dermal route of administration):

"If the new formulation contains a drug substance that has not been evaluated for ocular irritation, then the potential of the topical drug product to induce irritation of the eyes if the eyes were inadvertently exposed to the product should be appropriately addressed. The topical drug product's ocular irritation potential should be evaluated through the use of appropriate *in vitro* or *ex vivo* methods. The *in vivo* rabbit ocular irritation test method is no longer recommended for topical drug products."

Full text: 1.usa.gov/1SScyWY

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## USA: 2016 Alternatives Research Grant Program

The Alternatives Research & Development Foundation, a U.S. leader in the funding and promotion of alternatives to the use of laboratory animals in research, testing, and education, is currently soliciting research proposals for its 2016 Alternatives Research Grant Program. For over 20 years, this innovative program has created opportunities for scientists who have interest and expertise in alternatives research.

- Up to $40,000 in funding available to support individual projects
- Preference given to U.S. universities and research institutions
- Preference given to projects that use pathway-based approaches as exemplified by the 2007 National Academy of Sciences report, Toxicity Testing in the Twenty-first Century: A Vision and A Strategy

Deadline:
Applications must be electronically submitted or postmarked by May 2, 2016
Recipients notified: July 18, 2016

Criteria:

- Potential to significantly replace or reduce laboratory animals
- Scientific merit and feasibility

To apply, please download the Guidelines for submission and Application cover page at http://ardf-online.org/

Alternatives Research & Development Foundation
http://ardf-online.org/

## USA: Applications accepted for graduate fellowships for alternatives to the use of animals in science

The International Foundation for Ethical Research (IFER) is now accepting pre-proposal applications for 2016-2017 Graduate Fellowships.

IFER Graduate Fellowships are one-year grants of up to $15,000 (up to $12,500 in stipendiary support and up to $2,500 for supplies) apiece for projects that support the development, validation and implementation of innovative scientific methodologies that advance science and replace the use of animals in research, testing or education. Grants are renewable annually for up to three years, dependent on student progress and availability of funds.

By funding early career researchers with an interest in developing innovative alternatives to animal experiments, IFER hopes to seed the scientific field with talented individuals prepared to integrate scientific discovery with ethics and respect for animals.

Recipients of IFER Graduate Fellowships, selected by IFER's Scientific Advisory Board, have the potential to positively change the course of science by working to promote the advancement of humane methodologies that can spare animal suffering. Since 1985, grants totaling more than one million dollars have been awarded to promising young researchers who are developing alternatives to the use of animals in science. More information on the IFER Graduate Fellowship program, including eligibility requirements, submission guidelines and downloadable applications, can be found on the IFER website at http://www.ifer.org/fellowships.php.

Deadline for applications: 5:00 pm CDT on April 29, 2016.
Contact: ifer@navs.org

# USA: New EPA guidance for testing pesticides will reduce animal testing

On March 17 the U.S. Environmental Protection Agency announced the release of two guidance documents that will reduce animal testing.

The guidance document "Process for Establishing & Implementing Alternative Approaches to Traditional in Vivo Acute Toxicity Studies" (http://1.usa.gov/1RtzTz4) will expand the use of alternative methods for acute toxicity testing. The guidance describes a transparent, stepwise process for evaluating and implementing alternative testing methods (not using live animals) for acute oral, dermal and inhalation toxicity, along with skin and eye irritation and skin sensitization. EPA has incorporated comments from stakeholders, other regulatory organizations, and the scientific community. The agency's response to public comments is included in docket EPA-HQ-OPP-2016-0093 (http://1.usa.gov/1nZY3Dv).

The draft guidance "Retrospective Analysis & Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations" (http://1.usa.gov/1WATpHS) is being released for public comment. EPA expects that this guidance will lead to more data waivers for acute dermal studies for formulated pesticide products. EPA and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods conducted a retrospective analysis of oral and dermal acute lethality studies relevant to EPA's regulation of pesticides. This analysis, including 593 formulations and 316 active ingredients across numerous classes representing conventional pesticides, antimicrobials, and biopesticides, examined the utility of the acute dermal toxicity study for formulations in pesticide labelling for end-use products.

The agency used the analysis to support a draft policy to waive all acute lethality dermal studies for formulated pesticide products. EPA is accepting comments on the draft policy for 60 days, until May 16, 2016. Please submit any comments on the draft guidance to docket EPA-HQ-OPP-2016-0093 (http://1.usa.gov/1nZY3Dv).

These guidance documents are significant steps in the application of the Office of Pesticide Programs' strategic vision for implementing the 2007 National Research Council report on Toxicity Testing in the 21st Century.

Adapted from EPA press release
March 17, 2016