

## News

### EU: Clarification of relationship between Cosmetics Regulation and REACH

Since March 2013 there has been a ban in Europe on testing cosmetic ingredients in animals. However, some cosmetic ingredients are also used for other purposes and must therefore be registered as chemicals under REACH, the European Regulation on chemicals. Registration under REACH can require animal testing to fulfil the information requirements.

The relationship between the Cosmetics Regulation (Regulation (EC) No 1223/2009) and the REACH (Regulation (EC) No. 1907/2006) information requirements was clarified by ECHA in a Fact Sheet <http://bit.ly/1wvt7Lf> announced in the October 27, 2014 ECHA News alert, stating the following:

- Registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints, with the exception of tests that are done to assess the risks to workers exposed to the substance. Workers in this context, refers to those involved in the production or handling of chemicals on an industrial site, not professional users using cosmetic products as part of their business (e.g., hairdressers).
- Registrants of substances that are used for a number of purposes, and not solely in cosmetics, are permitted to perform animal testing, as a last resort, for all human health endpoints.
- Registrants are permitted to perform animal testing, as a last resort, for all environmental endpoints.

Therefore, the testing and marketing bans in the Cosmetics Regulation do not apply to testing required for environmental endpoints, exposure of workers and non-cosmetic uses of substances under REACH.

Registrants of substances registered exclusively for cosmetic use will still have to provide the required information under REACH wherever possible, by using alternatives to animal testing (such as computer modelling, read-across, weight of evidence, etc.).

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### EU: European Court of Justice to rule on use of non-EU animal cosmetics testing data

Although animal tests for cosmetic ingredients have been banned in the European Union (EU) since March 2013 (Regulation (EC) No 1223/2009), they are required for safety testing of cosmetics in other countries outside of the EU. As there are currently no validated methods to replace a number of safety tests required for cosmetic ingredients to be marketed in the EU, no new ingredients developed and registered purely for cosmetic purposes can be introduced to the European market at the present time.

In 2013 the European Federation for Cosmetic Ingredients (EFFCI) called on the High Court in London to clarify whether data gained from *in vivo* tests that are legal and required for the authorization of cosmetic ingredients in countries outside the EU can be used for authorization of new cosmetic ingredients in the EU. The High Court has now referred the judicial review put forward by EFFCI to the European Court of Justice (ECJ).

If the ECJ rules that data from non-EU cosmetic tests can be used in the EU, this would effectively render the ban in the EU useless as all required data could be attained by *in vivo* tests performed in non-EU countries.

This scenario is not covered in the ECHA Fact Sheet on the relationship between the Cosmetics Regulation and REACH discussed above in the ALTEX News.

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### EU: ECHA to do more to minimize animal experiments for REACH

On December 11, 2014 the European Ombudsman Emily O'Reilly, who is responsible for investigating complaints about the institutions of the European Union, informed the animal protection charity PETA that she agrees with PETA's complaint lodged in 2012 that the European Chemicals Agency (ECHA) "does not do enough to ensure that registrants of chemical substances refrain from performing unnecessary animal experiments in order to demonstrate their substances' safety" and found that ECHA's "interpretation of its obligations was excessively restrictive." The Ombudsman has made a friendly



solution proposal to ECHA concerning its role and its cooperation with Member States' authorities and received a positive response to this from ECHA.

Article 13 of the REACH Regulation states that "for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods." The Ombudsman considered that "such compliance checks can be used to verify whether the information submitted by registrants was generated in full compliance with the last resort principle." To this was added that the compliance check is not necessarily the only or most effective way to investigate potential breaches of Article 13. ECHA in fact suggested that direct contacts with the registrants concerned and direct cooperation with the relevant enforcement authorities of the Member States would be an alternative approach to tackling possible breaches.

As ECHA has no legal basis to reject a registration based on an animal test performed in violation of the Regulation, the Ombudsman proposed to ECHA to "systematically inform Member States of any registrant's refusal to supply compliant data following ECHA's finding, in the context of a compliance check, that the last resort principle has been violated" and that ECHA may also inform Member States "of possible instances of non-compliance ... in order to facilitate their enforcement tasks."

The full decision can be downloaded from <http://bit.ly/1KkWPdU>

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## EU: EFSA call for read-across methods for hazard characterization open

The European Food Safety Authority (EFSA) has published the call for proposals GP/EFSA/AFSCO/2015/01: New approaches in identifying and characterizing microbiological and chemical hazards.

The main objective of the call is to facilitate a scientific cooperation framework, the development and implementation of joint projects, and the exchange of expertise and best practices in the fields within the Authority's mission. In particular, the action financed by the EFSA grant to be awarded following the present call for proposals shall contribute to the objective of boosting scientific cooperation between scientists and research organizations with a competence in the development and validation of new approaches in the area of microbiological and chemical hazard assessment. It is of paramount importance to coordinate efforts between the food, veterinary and human health sectors in order to obtain maximum benefits from the use of whole genome sequence (WGS) and read across methodologies for microbial and chemical food safety, respectively.

Specific objectives of the call:

A) Making use of molecular approaches to identify and characterize microbial foodborne pathogens, specifically using whole genome sequence (WGS) analysis, to enhance the

understanding, the traceability and spread of the disease in humans that these bacteria populations may cause.

B) Development and application of read across methodologies to the hazard assessment of chemicals in the food safety area

Deadline: April 30, 2015

Information: <http://bit.ly/14uhBqO>

Adapted from EFSA Call  
GP/EFSA/AFSCO/2015/01  
November 11, 2014

## GER: Animal use decreased by 2.7%

The total number of vertebrates used in animal experiments in Germany in the year 2013 was 2,997,152. This figure is 2.7% (84,000 animals) lower than in the previous year. It is the first time the animal use numbers have decreased in the past 10 years in Germany.

The percentage of mice used for experimental purposes remained at 73%. After mice, rats (376,000), fish (203,000), rabbits (96,000) and guinea pigs (24,000) were the most commonly used species. While the number of mice, rats, rabbits, dogs, cats, pigs and birds was lower than in the previous year, the number of fish increased by 22%. 2,165 simians and prosimians were used for experiments in 2013; great apes have not been used for experimental purposes in Germany since 1991.

The number of genetically modified animals was 947,000, i.e., 32% of the total number of animals and 13,000 more animals than in 2012. 95% of these were mice.

The percentage of animals used for fundamental research increased by 3% to 40% of the total; 65,000 animals were used for education and training purposes, 5% more than the previous year. The number of animals used for the production or quality control of medicines or medicinal products for human medicine or veterinary use however decreased by 60,000, the use of animals for toxicological studies or safety testing decreased by 13,000 and the number of animals sacrificed for the removal of tissue decreased by 74,000 animals to 819,000 (these animals are also included in the total). The full report can be downloaded at <http://bit.ly/1D79oqz>.

According to Article 54 of Directive 2010/63/EU the Member States must collate statistical data on the use of animals for scientific purposes on an annual basis and make this data available to the public. From 2015 on Germany will provide these data in the designated European format. The comparability of the data to previous years will be limited owing to the new format.

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## GER: National Animal Protection Research Prize awarded

On December 4, 2014 Federal Minister of Food and Agriculture Christian Schmidt awarded the 33<sup>rd</sup> Animal Protection Research Prize, which carries prize money of €15,000, in Berlin. The prize was split between three winners:

Dr Uwe Marx of the Technical University of Berlin develops multi-organ-chips to replace animals in the safety testing of chemicals and in efficacy testing of drugs. These artificial systems aim to simulate the interaction of different organs by linking different compartments containing different cell types by the exchange of liquid.

Dr Peter Reinhardt of the Max-Planck-Institute for Molecular Biomedicine in Münster develops stem cell based models of neurodegenerative diseases such as Parkinson's Disease. Stem cells from the skin of patients are induced to become pluripotent stem cells (iPS). These are used to investigate the disease mechanisms and to test potential drugs.

The team of Prof. Dr Vera Rogiers of the University of Brussels has developed a stem cell based screening method to assess the toxicity of substances to the liver. Human stem cells are isolated from the skin and differentiated into liver cells.

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## GER: Center for alternatives to animal experiments to be established in Düsseldorf

The government of the State of North Rhine-Westphalia has decided to establish a center for alternatives to animal experiments (CERST-NRW) in 2015. The center shall have the aim to develop alternatives to animal testing to reduce the number of animal tests in the state. It shall be based at the Leibniz-Institute for Environmental Medicine (IUF) in Düsseldorf and will be headed by Prof. Dr Ellen Fritsche, a member of the board of ALTEX.

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## GER: Database of nontechnical project summaries publicly available

When the third amendment to the Animal Protection Law came into force in Germany on July 12, 2013 and the associated German regulation on the use of animals for experimental purposes came into force on August 13, 2013, it became obligatory in Germany to enclose a nontechnical project summary with every application to perform an animal experiment.

The competent authority sends the respective nontechnical project summaries of approved projects to the *Bundesamt für Risikobewertung* (BfR). These are published within twelve months in the public database AnimalTestInfo (<http://www.animaltestinfo.de>)

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## GER: 3Rs graduate school and research platform BB3R opened

The establishment of the Berlin-Brandenburg research platform BB3R with integrated graduate education will strengthen the 3R expertise of the region Berlin-Brandenburg. Intensive systematic research will provide substantial progress in 3R alternatives and excellent young scientists will be trained and highly qualified in alternative methods to animal experiments.

BB3R aims to accomplish the following goals:

- Establishment of alternative methods for preclinical drug development and basic research; facilitation of research collaborations and sustainable research activities in Berlin-Brandenburg
- Expansion of regional research activities by establishment of three junior research groups; successful candidates will be qualified for management positions in areas related to the 3Rs
- Sustainable establishment of the BB3R graduate school under the umbrella of the Dahlem Research School for structured training of graduate students who complete a specific mandatory course program on alternative test methods to animal experimentation and related fields in addition to the research project
- Creation of a pool of 3R experts for advice and assistance on BB3R research and administration
- Increasing the awareness of the society for 3R topics by open forums, by print and electronic media

The research platform BB3R and the established graduate school will fill substantial knowledge gaps in the 3Rs and alternatives to animal experimentation.

Speaker: Dr Monika Schäfer-Korting

<http://www.bb3r.de/en/projekt/index.html>

## GER: Animal Protection Research Prize 2014 of Hessen awarded

The Minister of the Environment for the State of Hessen, Priska Hinz, awarded the Animal Protection Research Prize 2014 of Hessen on November 18, 2014. The prize was split between two winners:



Prof. Dr Thorsten Stiewe of the Philips University in Marburg was awarded € 10,000 for his work on developing a method to monitor transplanted tumors in mice. The method allows monitoring of two different tumor cell populations *in vivo* by marking them with luciferases and detecting light emission in blood samples. The light emission is related to the total tumor size. This method reduces the number of animals needed for such studies, is less invasive than previous methods and can determine the size of the tumors more sensitively, allowing evaluations at earlier stages of tumor growth, thus refining the experiment.

Dr Stefan Weigt from Merck, Darmstadt received € 5,000 for his work on the development of an *in vitro* zebrafish embryo teratogenicity test. This test is based on a method previously developed by Dr Thomas Broschard and Francois Busquet to replace the use of rats and rabbits in determining the potential of substances to interfere with embryonal development. The improved method now reflects the entire embryonal development and no longer requires activation of the test substances by mammalian tissue, thus allowing a further reduction in the use of experimental animals. The test detects the teratogenic potential of the anticoagulant warfarin, which is false-negative in other *in vivo* and *in vitro* tests for teratogenicity.

The prize has been awarded since 2005 to scientists or companies that are scientifically active in the state of Hessen.

Adapted from press release 364  
Hessian Ministry for Environment,  
Climate Protection, Agriculture  
and Consumer Protection,  
November 18, 2014

awarded certificates after an extensive exam series to test their attitude towards animal experiments and knowledge gained after attending the workshop.

Detailed information regarding the course can be found at the undermentioned web address along with application forms, speakers and course details. <http://www.igib.res.in/sites/default/files/iclas/index.php>

Dr Vijay Pal Singh  
CSIR-Institute of Genomics &  
Integrative Biology  
Delhi, India

## INT: OECD guidance on reporting "non-guideline *in vitro* test methods" published

The OECD has published Guidance Document 211 for describing non-guideline *in vitro* test methods which can be found on the OECD website: <http://bit.ly/1Fln6rW>. The aim of the document is to harmonize reporting so as to enable regulators to assess the relevance of test methods and data quality of tests for which no formal guideline currently exists. It outlines the elements necessary for a full description of an *in vitro* method of low, medium or high throughput, so that results may be interpreted and assessed by regulators or scientists.

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## INDIA: 2<sup>nd</sup> International Course on Laboratory Animal Science

The CSIR-Institute of Genomics and Integrative Biology, New Delhi is going to organize the 2<sup>nd</sup> International Course on Laboratory Animal Science (ICLAS) from January 19-30, 2015. One of its kind, this course in collaboration with Laboratory Animal Ltd. (LAL), Utrecht University, The Netherlands and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) will provide an insight on conducting experimental studies on animals in an ethical manner. The course runs over two weeks, with extensive exercises for participants and modules of learning methods on the use of alternatives to animal experiments in research. A detailed module of the course has been designed on the basis of the Federation of European Laboratory Animal Science Association (FELASA) category C requirement to license laboratory animal users.

The course will help researchers to understand how to minimize the use of animals in research and how to perform experiments on animals with refined results and minimal pain to the animals. The course will cover ethical issues, statistical methods, alternatives to animal use in research, disease pathology and animal welfare as topics of discussion. Participants will be

## 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 on September 21 to October 2, 2015. 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.

Contact: [las@uu.nl](mailto:las@uu.nl)  
Internet: <http://www.uu.nl/lascourse>

## NOR: Norecopa launches 3R Guide database

3R Guide has been developed by Norecopa in collaboration with the Animal Welfare Information Center in Beltsville, USA. It is designed to help users locate resources which can be used to implement the 3Rs (Replacement, Reduction and Refinement) in animal experiments. The database can be accessed at <http://www.3RGuide.info>.

The Guide may be searched either with plain text, or by choosing Categories (e.g. Agricultural animals), Types (e.g. Databases) or 3R Relevance (e.g. Refinement). Items with a known Title may also be specifically searched for (search engines for authors and suppliers are under construction).

<http://www.3RGuide.info>

## UK: Funding bodies adopt “Responsibility in the use of animals in bioscience research” guidance

The EPSRC and AMRC charities are the latest research funders to adopt the guidance “Responsibility in the Use of Animals in Bioscience Research” and to join the NC3Rs peer review service. Implementation of the principles in this guidance is a condition of receiving funds from the funding bodies, which also include NC3Rs, BBSRC, Defra, MRC, NERC and Wellcome Trust.

The guidance sets out the expectations of the funding bodies for the use of animals in research and is therefore also useful to ethics committees, referees and Panel/Committee/Board members involved in reviewing research proposals. The guidance covers a summary of the legal controls on animal use, the responsibilities of the relevant parties, the principles and procedures of the funding bodies, and the requirements for research or collaborations outside of the UK.

Compliance with the guidance is assessed as part of NC3Rs involvement in the peer review processes of the UK funding bodies.

Download guidelines: <http://bit.ly/1xwBHeC>

Adapted from NC3Rs Newsletter  
December 15, 2014

## UK: NC3Rs launches resource on refinement and reduction of experiments with GA mice

In its resource hubs <http://nc3rs.org.uk/resource-hubs> the NC3Rs now also includes a section on experiments with genetically altered (GA) mice, advising scientists on how to improve animal welfare of GA mice, reduce the use of these animals and ensure a high quality of experiments to avoid duplication, e.g., by understanding the importance of the background strain and by controlling genetic drift. The resource shall be expanded with further articles on relevant topics.

This resource complements the list of current resources which includes animals in drug discovery and development, blood sampling, experimental design, housing and husbandry and the welfare of non-human primates.

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## UK: LUSH Prize 2014 awarded

In November the LUSH Prize was awarded to twelve winners from ten countries at a ceremony at the Royal Institute of British Architects in London. The prize money totaled £250,000 (€300,000).

The award ceremony was preceded by a conference entitled “Is One R the new Three Rs? Does the consensus building around 21<sup>st</sup> Century Toxicology – a wholly replacement model (‘1R’) – mean that the 3Rs framework (refinement, reduction, replacement) is an idea that has had its day? Or does a significant pathway-based understanding remain so distant, that 3Rs will retain a relevance for many years to come?” Slides from the presentations are posted online at <http://www.lushprize.org/2014-prize/lush-prize-conference-2014/>.

The winners of the LUSH Prize are listed below. Information on the winners can be found at <http://www.lushprize.org/2014-prize/2014-prize-winners/>.

### *Public Awareness*

- Humane Research Australia
  - Taiwan Society for the Prevention of Cruelty to Animals
- ### *Young Researchers*

- Henrik Johansson. Lund University, Lund, Sweden
- Jonathan Nicolas. Division of Toxicology/RIKILT Institute of Food Safety, Wageningen University and Research Centre, The Netherlands
- Rober Bachinski. Fluminense Federal University, Brazil
- Thit Aarøe Mørck. University of Copenhagen, Denmark
- Anne Krug. University of Konstanz, Germany

### *Science*

- Professor Roland Grafström and Dr Pekka Kohonen. Karolinska Institutet, Sweden





### Lobbying

- New Zealand Anti-Vivisection Society (NZAVS)
- CAAT-Europe (Center for Alternatives to Animal Testing)

### Training

- Professor Ovanes Mekenyan, Laboratory of Mathematical Chemistry, Bulgaria
- Africa Network for Animal Welfare

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## USA: Experimental animal numbers decrease by 6.5%

Research facilities registered with the United States Department of Agriculture are required to submit an annual report documenting their use of animals for research, testing, teaching and experimentation under the Animal Welfare Act. In comparison to statistics from Europe, these reports do not include mice, rats or birds used for these purposes. These animals have been included in the Animals Welfare Act, but with the exception of those bred for research purposes. The AWA does also not include cold-blooded animals such as fish and reptiles.

The total number of animals reported covering all States for 2013 was 891,000; this is 6.5% less than in 2012 and continues a decreasing trend started in 2011. Animals most commonly used were guinea pigs (191,000), rabbits (170,000) and hamsters (137,000). About 24,000 cats, 68,000 dogs and 64,000 non-human primates were used in 2013. Of the total number, 32% were subjected to painful experiments with analgesics and 10% were submitted to painful experiment without the use of analgesics.

Considering that in Germany (see News above) mice, rats, fish and birds, which are not covered in the US numbers, make up 94% of animals used for scientific purposes, it is difficult to estimate how high total use of experimental animals is in the US. If the ratios of animal species were similar to those in Germany, the total figure would be around 18 million animals, however as animal experiments on these species need not undergo any approval process or ethical evaluation, the number is likely to be far higher.

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## USA: SOT awards for animal testing alternatives announced

The Society of Toxicology has announced the winners of the SOT awards for 2015. Awards related to animal testing alternatives are:

- Marcel Leist, University of Konstanz and CAAT-Europe, will receive the 2015 SOT Enhancement of Animal Welfare Award (see also CAATfeed in this issue). This award honors a SOT member for contributions made to the advancement of toxicological science through the development and application of methods that replace, refine, or reduce the need for experimental animals. Dr Leist's laboratory focuses on *in vitro* toxicology, specifically mechanisms and systems related to neurotoxicity.
- Alfredo Miranda de Goes, Universidade Federal de Minas Gerais and Lei Li Kerr, Miami University, will receive a 2015 SOT Colgate-Palmolive Grant for Alternative Research. These grants of up to \$40,000 are awarded to scientists at any career level to support efforts that promote, develop, refine, or validate scientifically acceptable animal alternative methods to facilitate the safety assessment of new chemicals and formulations.
- Fabian A. Grimm, Texas A&M University, is being honored with the 2015 SOT Colgate-Palmolive Postdoctoral Fellowship Award in *In Vitro* Toxicology. This award of up to \$44,000 is designed to help postdoctoral trainees advance the development of alternatives to animal testing in toxicological research.
- Praketa Shimpi, University of Rhode Island, is being awarded a 2015 SOT Colgate-Palmolive Award for Student Research Training in Alternative Methods. This award provides students with the opportunity to receive training using *in vitro* methods or alternative techniques to reduce, replace, or refine the use of animals in toxicological research.

All 2015 SOT Award recipients will be honored at the Society's 54<sup>th</sup> Annual Meeting & ToxExpo in San Diego, CA on March 22-26, 2015.

Adopted from SOT press release  
December 9, 2014