News

EU: Commission responds to European Citizens' Initiative "Stop Vivisection"

The European Commission on June 3, 2015 responded to "Stop Vivisection," the third European Citizens' Initiative (ECI), which asked the Commission "to abrogate Directive 2010/63/EU on the protection of animals used for scientific purposes and put forward a new proposal aimed at phasing out the practice of animal experimentation, making compulsory the use – in biomedical and toxicological research – of data directly relevant for the human species." The ECI had collected 1,173,130 valid signatures.

The communication states that the EU is committed to animal welfare as well as protecting human health and the environment. It offers that the EU shares the conviction that animal testing should be phased out and proclaims this to be the ultimate goal of EU legislation. However, it holds that Directive 2010/63/EU and the Cosmetics Regulation EC No 1223/2009 "are among the world's most advanced pieces of legislation concerning animal welfare." It continues to state that where there are no full replacements of animal experiments a ban of these would export the research to other countries where welfare standards may be lower and would conflict with the objective to protect human and animal health and the environment.

The Communication further describes the role of animal studies and the EU's contributions to phasing out animal experiments through the stipulations of Directive 2010/63/EU, EU research into alternative approaches, validation and practical support for promotion of alternatives to animal use and international cooperation. It states that Directive 2010/63/EU has not been in force long enough to evaluate its effectiveness and that it will be reviewed only in 2017 and an implementation report is due in 2019.

Although so refusing the primary objective of the ECI to repeal Directive 2010/63/EU, the Commission commits to taking the following actions:

– to present by end of 2016 an assessment of options to enhance knowledge sharing among all relevant parties through communication, dissemination, education and training.
– to closely cooperate with Member States and international organizations with support from EU programs to support the development, validation and implementation of alternative approaches for regulatory and research use.
– to monitor compliance with the Directive and monitor correct enforcement by all Member States. By end of 2016 regulatory requirements in sector legislation will be examined to assess whether the up-take of available alternative approaches is efficient.
– to facilitate an efficient dialogue in form of a conference organized by end of 2016 on how to exploit advances in science to develop non-animal approaches and proceed towards phasing out animal testing. Progress on all above actions shall be reported at the conference.

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EU: DB-ALM updates information content on QSAR methods

Ten new reports have been published in the JRC QSAR Model Database that uses an internationally recognized format to provide key information on models which are all peer-reviewed before publication. The new reports refer to the following topic areas:

– six reports for the main endpoint *Human health effects* with the following QSAR inventory numbers: Q35-50-46-429; Q32-48-43-426; Q32-48-43-425; Q31-47-42-424; Q29-44-39-423; Q28-43-38-420
– four reports for the main endpoint *Ecotoxic effects* with the following QSAR inventory numbers: Q33-49-44-427; Q34-49-44-428; Q19-46-41-422; Q30-45-40-421

The complete list of published QSAR models (80 in total) can be freely downloaded from the JRC QSAR Model Database list of published reports at http://bit.ly/1R3zYDQ.

More information on QSAR models and free download of all published QSAR reports can be obtained directly from the JRC QSAR Model Database at http://qsardb.jrc.ec.europa.eu/qmrf/

DB-ALM Newsletter
April 2015

EU: ECHA Board of Appeal annuls order to perform animal test

A decision to request an Extended One Generation Reproductive Toxicity Study (EOGRTS) was annulled by the ECHA Board of Appeal, stating that in this case, the Agency did not "take account of all the relevant facts and circumstances in balancing the need for administrative efficiency with the obligations placed on the Agency" to ensure that testing on vertebrate animals is a last resort. It was found that the registration dossier contained information of another registrant for the same substance that had not been taken into account owing to the Agency applying a cut-off point for considering new information. As a result the Board of Appeal found that it was possible that the registrant may undertake animal testing unnecessarily.

Adapted from ECHA e-News
June 10, 2015

EU: Three BASF appeals against ECHA orders to perform PDT studies

In 2015, BASF SE Germany and BASF Pigment GmbH have together contested three decisions by ECHA requesting a pre-natal developmental toxicity study to satisfy the endpoint at Section 8.7.2 of Annex IX. In the appeals it is stated that weight of evidence approaches were employed to satisfy the pre-natal developmental toxicity study endpoint and that data justifying this approach were included in the respective registration dossiers but that ECHA did not assess whether the data submitted satisfies the waiving criteria. The appellants refer to a 2013 webinar recommending the use of a weight of evidence approach and establishing criteria for it. They further submit that the ordered studies are in breach of Article 25(1) and Recital 47, which respectively state that vertebrate animal testing is to be a "last resort" and that reduction, refinement and replacement of testing on vertebrate animals is necessary.

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EU: ECHA publishes advice on using non-animal skin sensitization tests

The new non-animal test guidelines each address a specific key event in the adverse outcome pathway for skin sensitization, describing the main biological steps in skin sensitization. They are relevant for many registrants preparing for the 2018 REACH registration deadline and, if used correctly, can replace the need to use animal test methods.

The adopted OECD test guidelines are:
– 442C: *In Chemico* Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA), and
– 442D: *In Vitro* Skin Sensitisation: ARE-Nrf2 Luciferase Test Method (Keratinosens™).

The draft OECD test guideline is:
– *In Vitro* Human Cell Line Activation Test (h-CLAT).

Registrants should get familiar with the advice and consider whether they could use the new methods instead of *in vivo* skin sensitization test methods. Due to the complexity of skin sensitization, the methods should be used as a combination in an integrated approach to testing and assessment. The non-animal methods may not be suitable for all substance types and where it is justified *in vivo* tests may still be necessary.

ECHA's guidance R.7a is being updated and will be published in 2016. It will give more detailed advice on how these non-animal testing methods can be used for REACH.

ECHA/NA/15/12

GER: Recommendation for animal protection class actions on a national level

The latest report of the scientific board for agrarian policy of the Federal Ministry of Food and Agriculture published in March strongly recommends the introduction of class actions for animal protection on a national level. Such class actions can currently be submitted by registered animal protection organizations in seven states (Baden-Württemberg, Bremen, Hamburg, North Rhine-Westphalia, Rhineland-Palatinate, Saarland and Schleswig-Holstein). However, with regard to animal experiments the registered animal welfare organizations are only informed of applications after they have been approved, and only an action for a declaratory judgement is possible, no right to participation or right to action. Baden-Württemberg is the only state that also limits class actions to very large animal holdings. Lower Saxony is currently discussing legislation to introduce class actions for animal protection.

The report (http://bit.ly/1LZlvLW) states that experience with the animal protection class actions to date has been positive, allowing the courts to more closely define legal parameters, improve the legal certainty of the use of legal terms and so improve the implementation of the animal protection provisions. It goes on to declare that an introduction of the legislation on a national level would be of benefit in terms of legal and economic unity.

The call for an introduction of class actions for animal protection is echoed by a position paper published by the Social Democratic Party (SPD), one of the two ruling coalition parties (http://bit.ly/1LnDUxr), in June.

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GER: Update of SATIS ethical ranking of universities published

An ethical ranking of German universities was first performed in 2010 to guide students who object to animal use in education in their choice of university. All faculties for biology, medicine, veterinary medicine and later also nutritional science were asked about their use of animals in bachelor and preclinical studies. A partially updated version of the ranking published in April 2015 is available at http://bit.ly/1G2Mezf.

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SUI: News from ALTEX

Mardas Daneshian, CEO of CAAT-Europe was voted the new president of the Society ALTEX Edition at the last board meeting on June 19. Beatrice Roth, scientific officer for animal experiments at Zürcher Tierschutz was voted vice-president.

Mardas' first official duty was to inform Sarah E. Cavanaugh, formerly of the Physician's Committee for Responsible Medicine, that she has won the ALTEX Prize for her 2014 article, authored with John J. Pippin and Neal D. Barnard, "Animal Models of Alzheimer Disease: Historical Pitfalls and a Path Forward" (ALTEX 3/14, http://dx.doi.org/10.14573/altex.1310071).

The Prize consists of a CHF 2,000 personal prize and a contribution to travel expenses to the EUSAAT 2015 Congress in Linz, Austria, where the award will be presented. The members of the Board, Editorial Board and Editorial Office elected the winner of the annual prize out of all main articles published in 2014; articles including members of the ALTEX Board and Editorial Office as first or last authors were excluded.

The Thomson Reuters Journal Citation Report 2014 was released in June. ALTEX' impact factor rose to 5.467 – the highest yet. The five-year impact factor is now 4.917.

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TAIWAN: Bill to ban animal testing for cosmetics launched

A bill to ban animal use in the testing of cosmetics in Taiwan was launched by a legislator together with the Taiwan SPCA (for the #BeCrueltyFree Taiwan campaign) in the Taiwanese Parliament in April 2015. The bill seeks to ban animal tests for finished product testing after one year, for semi-finished and ingredient testing after two years and to ban sales of products tested on animals after three years.

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UK: Delivery report on reduction of animal use in scientific research published

The United Kingdom Home Office and partner agencies published a report, "Working to Reduce the Use of Animals in Scientific Research: Delivery Report" in March 2015 (http://bit.ly/1J13XNz). The document follows up on the progress on three strategic objectives set out in a February 2014 "Delivery Plan," i.e., advancing the use of the 3Rs in the UK; influencing the uptake and adoption of 3Rs approaches globally; and promoting an understanding and awareness about the use of animals where no alternatives exist.

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UK: LUSH Prize nominations open

On April 24, World Day for Animals in Laboratories, the fourth LUSH Prize was announced. 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 nominations from all over the world.

Further information: http://www.lushprize.org/awards/
Deadline for nominations: July 24, 2015

Adapted from Lush Prize Newsletter
April 2015

UK: Research Councils' guidance for funding of animal research updated

The Research Councils and the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) have reviewed and aligned their guidance to clarify for researchers what information they are expected to provide to allow robust evaluation of applications for funding involving animal research.

The Animal Research section on the Joint Electronic Submission System (Je-S) has been altered to reflect these changes.

All proposals using animals should explain not only the need to use animals and the ethical implications of the planned experiments, but also clearly describe how the planned experimental design is appropriate to give robust results. In explaining the latter, applicants are expected to detail how the number of animals to be used was decided, plans to minimize experimental bias, and provide information on statistical aspects of the study including statistical power and appropriate statistical analysis.

Detailed information about what should be included is provided in the respective Research Councils' guidance for grant applicants.

A number of important related initiatives have aimed to improve the reproducibility of animal experiments and the application of the 3Rs (replacement, reduction and refinement), as well as raising the sometimes inadequate standard of reporting of animal experiments in the scientific literature.

The guidance document "Responsibility in the use of animals in bioscience research" (http://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research), coordinated by the NC3Rs and the Research Councils, along with Defra, the Wellcome Trust and other members of the Association of Medical Research Charities (AMRC), sets out the funders' expectations, principles and procedures as well as the legal controls and the responsibilities of relevant parties. This includes a requirement to follow the NC3Rs' ARRIVE guidelines (http://www.nc3rs.org.uk/arrive-guidelines), which lay out criteria that should be met in reporting animal studies in order that their results and conclusions can be properly evaluated and utilized.

Excerpt from
Research Councils UK
Announcement 150415

UK: NC3Rs 2014 3Rs Prize for modeling approach to reduce animal use

Oliver Britton, a PhD student at the University of Oxford, was awarded the NC3Rs 2014 3Rs Prize for his paper "Experimentally calibrated population of models predicts and explains intersubject variability in cardiac cellular electrophysiology" (http://dx.doi.org/10.1073/pnas.1304382110). The judges found that the work had high potential to reduce animal use especially in the safety assessment of new drugs.

The prize, which was awarded on March 9, 2015, consists of a £18,000 research award and a £2,000 personal award sponsored by GlaxoSmithKline. Highly commended entries receive a £4,000 grant and £1,000 personal award.

Adapted from
NC3Rs Newsletter
March 2015

USA: New York County Supreme Court to rule on chimpanzees' right to liberty

The Nonhuman Rights Project (http://www.nonhumanrights project.org/) on May 27, 2015 argued in the New York County Supreme Court that the chimpanzees Hercules and Leo should be granted the right to bodily liberty as they are autonomous and self-determined beings. Stony Brook University thus should be ordered to release them from the laboratory. Although no animal has yet been granted freedom through *habeas corpus*, the judge stated that the "common law evolves through new discoveries and social mores" and that judiciaries are obliged to at least consider whether a class of beings may be granted a right.

The Nonhuman Rights Project seeks to achieve a change in legal status for nonhuman animals from "things" without legal rights to "persons" with the rights of bodily integrity and bodily freedom. Further court cases are pending.

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