EU: Progress on alternative approaches to animal testing

The European Partnership on Alternative Approaches to Animal Testing (EPAA) was launched in November 2005 by European Commission Vice President **Günter Verheugen** and Science & Research Commissioner **Janez Potočnik** together with the European industry. At a conference in Brussels (6th Nov. 2009) both industry and the Commission have expressed their strong wish to strengthen this unprecedented collaboration to reduce animal testing as much as possible to avoid unnecessary suffering for animals (the 3Rs Approach) wherever possible.

Vice-President Günter Verheugen, Commissioner for Enterprise and Industry, and Science & Research Commissioner Janez Potočnik jointly stated: "The launch of the EPAA in 2005 reflected our strong view that alternative approaches in regulatory testing had to be prioritised in order to improve the safety and quality of human lives whilst causing the minimum harm to animals in scientific experiments. Indeed we have an ethical obligation to avoid their unnecessary suffering. Consequently, policy makers and industry have engaged in a constructive partnership to do their utmost to develop methods that reduce, refine and replace animal testing. Our common vision has already produced tangible results."

Research on alternative approaches is the key to implementing the 3Rs of replacement, reduction and refinement. Both the European Commission and industry devote significant resources to Research & Development (R&D) to align priorities and initiate projects that will lead to less and better use of animal testing:
For instance,

- EPAA companies volunteered to provide data for adapting an extended one generation study, originally developed for plant protection products, for use in other sectors as well, thus reducing the animals used in traditional two-generation studies.
- New innovative approaches to provision of the key toxicological information without the use of animal models. Work continues on the use of stem cells and computational chemistry and systems biology.
- EPAA data bases promote cross-sector sharing of In-house methods to identify opportunities for technology transfer and to identify current research gaps. Thus animal testing can be reduced.
- To promote the uptake of alternative methods in regulation, the European Commission and EPAA companies have developed protocols for cooperation, identified priorities for data communication and developed recommendations for speeding up regulatory uptake. Furthermore, projects were launched on:
- How to best use and combine data from different sources to replace traditional animal testing and to promote Integrated Testing Strategies for regulation.
- Innovative testing procedures in vaccine batch release testing, in order to replace as possible *in vivo* tests with *in vitro* tests.
- Ways to promote international cooperation on alternative approaches, now a standing item on the agenda of the EU regulatory dialogue with international trading partners.

Under its 2009 lead theme, dissemination of 3R information, the EPAA has carried out a market survey on information needs and ways to enhance dialogue between regulators and method developers. A congress report about the 2009 annual meeting of EPAA in Brussels, 6th November 2009, concerning "Dissemination of 3Rs information" will be published in ALTEX 1/2010.

More information:
The European Partnership for Alternatives to Animal Testing
http://ec.europa.eu/enterprise/epaa/index_en.htm
Research: Alternative Testing Strategies supported by the EU
http://cordis.europa.eu/documents/documentlibrary/106691831EN6.pdf
ECVAM (European Centre for the validation of alternative methods)
http://ecvam.jrc.ec.europa.eu/
TSAR (Tracking System for Alternative test methods in the context of EU chemical legislation)
http://tsar.jrc.ec.europa.eu/

EU: New EU FP7 coordination and supporting action project *AXLR8 (=accelerate)*, 2010-2013

It is the goal of *AXLR8* to accelerate the transition to a toxicity pathway-based paradigm for chemical safety assessment through internationally co-ordinated research and technology development.

AXLR8 is designed to fulfil the growing need of a focal point for coordination among 3Rs research projects in Europe as well as internationally.

AXLR8 will provide tools and opportunities for increased networking, information exchange, problem solving, strategic planning and collaboration among a variety of scientific disciplines and stakeholder groups with the goal of accelerating the transition toward "21st century" approaches in toxicology and risk assessment.

The *AXLR8* project aims to support the transition to a toxicity pathway-based paradigm for quantitative risk assessment and will:

1) *Organise a series of annual workshops* to map research progress, gaps and needs in the FP6/FP7 programme on alternative testing strategies.
2) *Provide a range of tools and opportunities for enhanced interdisciplinary and international communication*, coordination and collaboration in order to maximise the impact of available resources.
3) *Work to streamline regulatory acceptance* procedures to provide for the uptake of validated 3Rs methods, including a smooth transition to 21st century systems as they become available.
4) *Produce annual progress reports* on the state of the science, including recommendations on priority research and funding targets, in order to ensure a prominent role for European science in this rapidly developing global research area.

Specifically, the *AXLR8* project strategy foresees:

1) *Creation of a Scientific Panel* to independently monitor the progress reports of EU-funded 3Rs projects as a basis for planning annual scientific workshops.
2) *Pro-active outreach to EU regulators and other end users of 3Rs methods* to ensure they are kept informed of R&D-level activities and that their needs and considerations are communicated to and understood by method developers.
3) *Hosting of three scientific workshops to bring together FP6/FP7 project coordinators and international scientists*, as well as regulatory and corporate end-users of 3Rs methods, to discuss the progress of ongoing activities, identify knowledge gaps and opportunities for synergies, and recommend priorities for future EU research and funding calls.
4) *Preparation of annual AXLR8 reports* to highlight for the public, policy makers and other stakeholders the achievements and benefits of the EU's investment in science to advance the 3Rs.
5) *Dissemination of project results* via a dedicated project website AXLR8.eu, periodic e-newsletters, and other means.

The five project work packages (WP) have been designed in accordance with this overarching strategy.

The consortium of *AXLR8* is formed by

1) the coordinator Freie Universität Berlin (FUB), Berlin, Germany:
   Horst Spielmann (scientific coordinator) & Monika Schäfer-Korting
2) the Humane Society International (HIS), London, UK:
   Troy Seidle & Emily McIvor
3) CARDAM (Centre for Advanced R&D on Alternative Methods) at VITO, Mol Belgium:
   Greet Schoeters
4) the secretariat at FUB:
   Vivienne Kral

hsp

FIN: The Finnish Centre for Alternative Methods FICAM

At ZEBETs 20 years anniversary in Berlin, Tuula Heinonen presented the new finnish centre. It will be an innovation chain from science to commercial products. The Finnish Centre for Alternative Methods FICAM is a centre of excellence on alternative methods. It's key expertise is cell and tissue research and it is developing validated 3D tissue models to supplement or replace animal experiments based on own innovations or co-operation with other research groups. FICAM and its research personnel is located at the Medical School of University of Tampere.

FICAM's activity areas are

- Angiogenesis
- Endometrium model to test hormonal responses
- Mammary gland model to test hormonal responses
- Neurotoxicity models
- Barrier models
- Cancer models
- Basic cytotoxicity models
- Methods will be validated

FICAM's basis lays on the multi-science network on cell and tissue technology in Tampere

University of Tampere

- Basic and applied science
- Cell research
- Pharmacology

Tampere University Hospital
- Tissue bank
- Clinical medicine
- Patient information

Services
Expertise, information sharing and training. FICAM has experience in research and development on alternative methods for more than 10 years. The Centre has basic infrastructure from laboratory space to instrumentation that fulfil GLP requirements.

Services provided by the FICAM
- Expertise on validation of alternative methods
- Expertise on GLP (Good Laboratory Practice)
- Information sharing
- Advanced training courses to industry and others outside the university

Benefits of the alternative methods
Economical, ethical, efficient
- Not using living animals
- Results from animal experiments are not necessarily applicable to man
- Tests based on human tissues and cells model directly the effects in man
- Alternative tests are applicable to test efficacy and safety of, e.g. pharmaceuticals, cosmetics, industrial chemicals
- Costs of *in vitro*-tests are only a fraction of that of animal experiments
- Alternative tests are fast and they can be automated
- Mathematical modelling, e.g QSAR

Key strengths of alternative method activity in Finland
- For more than 10 years experience in research and development on alternative methods
- Centre may act as the National Reference laboratory for method validations of ECVAM
- Internationally high-standard research and information technology
- Scientific computing resources
- Uniform procedures of a high quality

Clients
Searching co-operation
Because of the new European Community Regulation on chemicals and their safe use REACH, Pharmaceutical industry needs tests in discovery that models effects in man and also cosmetic industry urgently needs alternative methods. To get validated alternative methods soonest possible in use to replace and supplement animal experiments substantial efforts, financial support and extensive co-operation are needed among different stakeholders.

FICAM's co-operation target groups
- Research institutions and research groups
- Pharmaceutical industry
- Authorities
- *In vitro*. Testing in/with
  - Buffer or other solution
  - Tissue homogenate
  - Cell line cells, originating from cancer
  - Differentiated cells, originating from stem cells
  - Isolated cells from tissues (animals, human)
  - Tissue explants
  - Tissue models

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KO: KoCVAM founded

World-wide restrictions on animal use for research have driven efforts to develop alternative methods. Joining international 3R trends, a Korean Society for Alternatives to Animal Experiments (KSAAE) was started in 2007. KSAAE has organised various academic activities, such as hosting winter and summer conferences, publishing the society's journal, and exchanging information on alternatives with other countries including Japan and China. The National Institute for Toxicological Research has supported alternatives in Korea through sponsoring KSAAE, preparing the foundation of KoCVAM (Korean Center for Validation of Alternative Methods), and performing research activities for the development of alternative methods. Alternative methods under development can be internationally validated among Asian countries belonging to the Asian Coalition for Alternatives, which will facilitate world-wide adoption of the methods. The development of new alternative methods will be efficiently enabled by mutual research funding among Asian countries. The dissemination of scientific knowledge on alternatives shall be supported by joint conferences and publication of a scientific journal. Furthermore, education of young scientists in alternatives will be achieved at regular conferences or by sending students on exchange to advanced institutes.

Press release KoCVAM,
Seoul, 3rd November 2009

UK: FRAME chairman issues stark warning

Fifty years after the principles of humane treatment for laboratory animals were first set out too little is being done to introduce non-animal tests into research.

That was the warning issued by Chairman of Trustees of the Fund for Replacement of Animals in Medical Experiments (FRAME) Michael Balls. Speaking at a conference in Germany he said that European legislation is driving laboratory work backwards in terms of animal use.

Authors William Russell and Rex Burch set out the Three Rs system in their book *The Principles of Humane Experimental Technique* in 1959. It said that, wherever possible, animal tests should be replaced with valid alternatives; if animals had to be used their numbers should be *reduced* to an unavoidable minimum and their treatment *refined* to ensure them the least possible pain and distress.

But Michael Balls said none of the Three Rs was being fully applied in spite of being suggested so long ago. He said: "Refinement seems to have been used as a convenient way of ensuring that animal experimentation is seen as respectable and can be allowed to continue, while the fundamental ethical questions are avoided."

"The effort put into a dedicated search for Replacement alternatives has been woefully inadequate. The significance of the high fidelity fallacy – the idea that animals that are most like humans are likely to give the most reliable results in experiments – has not been recognised. "Europe is going backwards, at great cost to the opportunities offered by the Three Rs. The science is being driven by the politics, even to the point of corrupting the validation process. There is a danger that, rather than having to be independently shown to be reliable and relevant for their stated purposes, replacement alternative tests will be accepted because they are 'suitable' – that is, politically convenient."

He cited the proposed new European REACH legislation (Registration, Evaluation and Authorisation of Chemicals) as one example. The proposal to tests thousands of chemical substances manufactured or imported into the EU in quantities of 1 tonne per year or more has been estimated to need millions of laboratory animals to meet requirements.

He called the plan "totally unworkable, proposed by ill-informed, ambitious civil servants, taken up by ill-informed, ambitious politicians, and then by ill-informed, ambitious governments."

He called the new 7th Amendment to the Cosmetics Directive "a ruse of no value, seemingly designed to convince politicians and a gullible public that something is being done."

And blasted a further piece of proposed legislation – the draft proposals to replace Directive 86/609/EEC – "surely one of the worst pieces of draft legislation ever published, which even foresees circumstances in which Member States could permit experiments on Great Apes."

He called for several changes to bring about more humane science. "Genuine commitment to the Three Rs is needed, leading to identifiable Reduction should be achieved without further delay, through better experimental design and statistical analysis.

"Refinement, however welcome, should not be seen as an end in itself. Replacement is overwhelmingly the most important R. Much greater resources should be invested in the dedicated search for replacement alternatives."

Michael Balls was speaking at a conference in Berlin, Germany to celebrate the 20th anniversary of ZEBET (Centre for Documentation and Evaluation of Alternatives to Animal Experiments) at the German Federal Institute for Risk Assessment (BfR) and the 50th anniversary of the 3Rs Principle.

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USA: IIVS Update

The Interplay Among Need, Motivation, and Existing Regulations for a Validated In Vitro Mucosal Irritation Method

The 7th Amendment of the EU Cosmetics Directive 76/768/EEC, has established timeframes and milestones for banning traditional animal tests for many pertinent endpoints such as skin and eye irritation, sensitization, genotoxicity, and phototoxicity for the safety assessment of cosmetics. This means that reliable and relevant non-animal methods have to be developed, validated and finally accepted by the relevant authorities to continue to assure the safety of new cosmetics ingredients. Over the last several years we have seen the successful replacement of many of these animal tests. We can now apply our learnings from developing these promising replacement models, to virtually identical toxicities, still requiring animals, which are used to assess new drugs, medical devices, bulk chemicals, etc.

One area that needs attention is testing for mucosal irritation, which is often used by personal care product manufacturers, and is required for many FDA regulated products. Today, the most frequently used test for acute vaginal mucosal irritation is the *in vivo* rabbit vaginal irritation (RVI) model – currently the only test accepted by U.S. FDA for regulatory submissions of products intended for mucosal tissue contact such as medical devices and microbicides. The RVI method consists of

inserting the test material for 10 days into the vagina of each of three rabbits followed by terminal sacrifice and histopathological examination. The test is often criticized on humane grounds and for scientific reasons – a large part of the rabbit vagina is structurally distinct from that of the human. However, at the global regulatory level, few alternative methods for vaginal irritation have been proposed for a validation program to determine the safety of pharmaceutical, cosmetic or personal care products.

Is there a need and motivation to validate a vaginal irritation model?
Cosmetic and personal care products that are specifically formulated for application onto human external mucosa can induce undesirable local or systemic side effects after unintended entry into the vagina. The safety of these products is almost always determined in the animal model. However, assuring the safety of products without animal testing is a goal common to many personal care product manufacturers. A reliable and relevant in vitro alternative for the RVI assay would satisfy this goal.

What is or can be done to move the alternatives field toward a validated mucosal irritation model and protocol?
Previous successes in developing in vitro replacements for irritation endpoints in the cosmetics area indicate that 3D tissue models comprised of human cells would be the logical approach for mucosal irritation. Already, product development groups within personal care and cosmetic manufacturers are applying a time-to-toxicity approach with reconstructed tissues to estimate safety. For many of these companies the tissue platforms allow for the screening of raw materials, rank ordering irritancy of candidate formulations and the development of increasingly milder products. Through its extensive experience IIVS can assist both the product development testing needs and validation efforts in this area. Currently, manufacturers of 3D models for mucosal irritation have begun a few evaluation programs. MatTek (Ashland, MA, USA) has reported a pre-validation program for its EpiVaginal™ tissue model, and Skinethic (Nice, France) has reported the use of its human vaginal epithelium (HVE) model as a model for *Candida albicans* research. For further success to occur in this area we encourage manufacturers of cosmetic and personal care products to join in these investigations of new tissue engineered 3D testing platforms. Coordinated validation studies targeted at gaining regulatory acceptance of *in vitro* assays for the assessment of mucosal irritation will ultimately benefit many different industries.

Gertrude-Emilia Costin, Ph.D.
IIVS Study Director

Meeting Report: "Considering Alternatives; Making a Difference"

A workshop jointly sponsored by the USDA, National Agricultural Library and the Animal Welfare Information Center was held on September 23-24, 2009 in Kansas City, MO. The workshop was designed to help Institutional Animal Care and Use Committee (IACUC) members, principal investigators and the general public better understand the Animal Welfare Act requirement to "consider alternatives." Over 50 participants came together to gain a familiarity of the 3Rs, the basics of database searching for alternatives, knowledge on how alternatives are implemented in research protocols and understanding the role of the IACUC in evaluating the consideration of alternatives. To support the goals of this workshop, Rodger Curren was asked to give a presentation titled, "Considering the 'Replacement' Alternative."

5th International Workshop on Genotoxicity (IWTG)

Aug 17-19, 2009 Basel, Switzerland
Consensus recommendations from four previous meetings of the IWGT have been highly influential in shaping revisions of OECD Test Guidelines. New challenges facing the genetic toxicology community were addressed at the 5th workshop including how to reduce the number of "false positive" results from standard *in vitro* test batteries and how to reduce animal usage. A new group led by Stefan Pfuller of P&G, *In Vitro Test Approaches with Better Predictivity*, developed consensus recommendations for better test systems to improve the predictivity of *in vitro* tests. The group reviewed current studies, many of which were funded by COLIPA. One new assay, developed by IIVS and P&G, that received strong recommendation was the micronucleus assay using three-dimensional human reconstructed skin. Data utilizing this new assay were presented by Rodger Curren. The formal recommendations (Group 4) are available at: www.iaems.net/iwgt.asp

European Chemical Agency (ECHA) Releases Clarification

In a statement of clarification, ECHA made clear that companies which need to provide information based on long term toxicity studies (90 day repeated dose toxicity study or a pre-natal developmental toxicity study) do not need to also submit the results of screening or short term studies in order for their submission to be considered complete. "Companies are encouraged to consult the Agency's Factsheet for the complete clarification to enable them to decide which information they need to provide for their dossiers." ECHA hopes that this clarification will avoid unnecessary animal tests and costs to industry. The Factsheet can be viewed at http://echa.europa.eu/doc/reach/reach_factsheet_testing.pdf

ZEBET Anniversary Celebration and Symposium

A two day symposium was organized to celebrate the 20th Anniversary of ZEBET and the 50th Anniversary of the publication of *The Principles of Humane Experimental Technique* by William Russell & Rex Burch. ZEBET has an international reputation as a leader in the development and validation of alternative toxicological methods. Their efforts have led to significant advances in the area of skin irritation, corrosion, and embryotoxicity as well as photoxicity and acute toxicity. In addition, ZEBET has helped develop the AnimAlt-ZEBET database – a full-text database of evaluated alternative methods to animal experiments in biomedicine and related fields.

Held at the Federal Institute for Risk Assessment (BfR) in Berlin, Germany,

the workshop opened with the presentation of the Annual Award of the Federal Government for Research on the Protection of Experimental Animals to Dr. Johanna Schanz of the Fraunhofer Institute. The symposium allowed colleagues who have worked closely with ZEBET to review their collaboration at the national and international level. ZEBET's significant contributions to the 3Rs during the past 20 years were shared from the perspective of international stakeholders such as members of industry, animal welfare organizations, regulatory authorities, the OECD and key groups such as IIVS, CAAT and FRAME. The symposium also included updates on noteworthy programs such as Toxicity Testing in the 21st Century, European Partnership on Alternative Approaches to Animal Testing and Evidence Based Toxicology. During the Anniversary Party, the participants were able to socialize and reflect on the many personal and professional collaborations that have been developed with the ZEBET members over the past 20 years. IIVS would like to thank members of ZEBET for their outstanding commitment to the advancement of the 3Rs and wish them continued success and collaboration.

Eye Irritation Update

Two Test Guidelines for the detection of severe or corrosive eye irritants were formally accepted by the OECD Council on September 7, 2009. The methods are the BCOP assay (TG437) and ICE assay (TG438). These test guidelines went through the OECD approval and acceptance process in one year – the fastest timeline to date. Both draft guidelines were initiated in the US by ICCVAM with cooperation from IIVS.

COLIPA is funding an eye irritation trial in conjunction with ECVAM that will assess two 3-dimensional tissue models, MatTek's EpiOcular and SkinEthic's HCE, for their ability to correctly identify mild and non-irritating materials. If successful, these models could be used in conjunction with the BCOP or ICE methods to cover the range of eye irritation and could be used to meet the requirements of the 7th Amendment to the Cosmetics Directive.

Bottom-Up and Top-Down Approach for Replacement of the Draize Eye Test

In a statement released in July, the Scientific Advisory Committee (ESAC) of ECVAM stated that in the foreseeable future, no single *in vitro* eye irritation test will be able to replace the Draize test. Instead, a strategic combination of several *in vitro* tests used in a tiered testing strategy may be used as a replacement. The concept for such a replacement strategy was developed at an ECVAM workshop. "The framework is based on alternative eye irritation methods that vary in their capacity to detect either severe irritant substances (EU R41; GHS Category 1) or substances considered non-irritant (EU Non – Classified; GHS No Category). According to this framework, the entire range of irritancy may be resolved by arranging tests in a tiered strategy that may be operated from either end: to detect first severe irritants and resolve absence of irritancy (Top-Down Approach) or to proceed inversely, starting with the identification of non-irritants first (Bottom-Up Approach). Mild irritancy will be resolved in a last tier in both approaches."

ECVAM has completed a retrospective study on four cell based *in vitro* methods to determine their usefulness in such a strategy. The formal recommendations are summarized below:

Cytosensor Microphysiometer: considered to be ready for consideration for regulatory use as an initial step within a Top-Down approach to identify ocular corrosive and severe irritants (water – soluble substances and mixtures only). The Cytosensor is also ready for consideration for regulatory use as an initial step within a Bottom-Up approach for water-soluble surfactants and surfactant containing mixtures only. However the Cytosensor does not correctly identify moderate and mild ocular irritants.

Fluorescein Leakage (INVITTOX Protocol 71 only): considered to be ready for regulatory use as an initial step within a Top-Down approach to identify ocular corrosives and severe irritants (water-soluble substances and mixtures only).

With respect to Neutral Red Release, Fluorescein Leakage (other protocols) and Red Blood Cell haemolysis assays, ESAC stated that there is insufficient evidence to support a recommendation that they should be considered for regulatory use. To view this and other statements from the Advisory Committee, please visit http://ecvam.jrc.ec.europa.eu/index.htm under "Publications/ESAC statements"

Upcoming Events

- Society of Toxicology Annual Meeting and Exhibit
Salt Lake City, Utah, USA
March 7-11, 2010
Visit IIVS at booth # 717

- Practical Methods for In Vitro Toxicology Training Course
June 15-17, 2010
IIVS Facility in Gaithersbrug, MD, USA

- 2010 In Vitro Alternatives Forum
October 18 -19, 2010
Old Town Alexandria, VA, USA

Please visit www.iivs.org for more information

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USA: Doctors and scientists create new society to promote non-animal toxicology testing methods

Inspired by a National Academy of Sciences report calling for a new toxicity testing strategy, the Institute for In Vitro Sciences, Inc. (IIVS) and the Physicians Committee for Responsible Medicine (PCRM) announce the formation of a new scientific society to promote the development and use of non-animal toxicological testing methods. This will be the first scientific society in North America devoted to such a mission.

The American Society for Cellular and Computational Toxicology (ASCCT) will provide an organized forum for discussion of cellular (*in vitro*) and computational toxicology approaches, especially as replacements for animal-based toxicology methods. Through regular meetings and activities, the Society will facilitate the development, acceptance, and routine use of cellular and computational methods by open dialog between industry, academic, advocacy, and regulatory scientists. The Society will strive to include the participation of young scientists to promote their contributions to the field.

IIVS and PCRM were inspired to create the Society by the surge of interest in toxicology since the publication of the 2007 National Academy of Sciences report, *Toxicity Testing in the 21st Century: A Vision and Strategy*.

"The strong commitment of American scientists to alternative testing methods is illustrated by the National Academy of Sciences report, increased Environmental Protection Agency funding for non-animal methods, and other recent developments," says Erin Hill, Vice President of Program Development for IIVS. "With several similar societies in Europe, Asia and South America, it is time for North American scientists to meet on a regular basis to share developments in the field."

While the two organizations plan to play an active founding role in the new Society, it is hoped other organizations will enthusiastically support its growth, says Kristie Sullivan, MPH, Scientific and Policy Advisor, PCRM. "We invite scientists from industry, regulatory agencies, and advocacy groups to become involved in the formation of the new society to ensure its success," says Sullivan. "Active participation will create a dynamic forum to share information and accelerate the development and use of *in vitro* and *in silico* methods, and help to make toxicology a more human-relevant – and more humane – science."

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Washington, Dec. 10, 2009
PRNewswire-USNewswire

CAATfeed

CAAT-EU – memorandum of understanding signed

In the last issue of CAATfeed we reported about the emerging plans for CAAT-EU as the first transatlantic organization for humane science and the paradigm shift in toxicology – a joint venture between the Johns Hopkins Bloomberg School of Public Health and the University of Konstanz, Germany. In the meantime, a memorandum of understanding was signed, and the project gained its first sponsors including BASF, Beiersdorf, L'Oréal and the Doerenkamp-Zbinden Foundation. Several others currently are finalizing their decisions and, we hope, will join as founding members in time for the inauguration, planned for March 30th, followed by the first board meeting on the 31st. Co-directors Marcel Leist and Thomas Hartung have appointed Dr. Mardas Daneshian as CEO. CAAT-EU's initial activities, in addition to the inauguration and board meeting, will include an information day on the US efforts toward a toxicology for the 21st century (Tox-21c), to be held in June in Konstanz, as well as a workshop for teachers of alternative approaches scheduled for fall (see also the *Food for thought* article on education in this issue of ALTEX).

CAAT chemical industry information day: November 11, 2009

CAAT's second information day, held Wednesday, November 11, 2009, in Baltimore, presented developing solutions for US industry as they work to comply with REACH. Speakers included Bennard van Ravenzwaay (BASF), Ralph Gingell (Shell), Bob Kavlock (US EPA), Rick Becker (American Chemistry Council), Sebastian Hoffmann (seh consulting+services, Cologne, Germany) and Tina Levine (US EPA), as well as Paul Locke and Thomas Hartung from

CAAT. Our partners from ThermoFisher Scientific (Martin Pietila), Life Technologies (Mark Powers), CeeTox, Inc. (James McKim), and Institute for In Vitro Sciences (IIVS, Hans Raabe) presented solutions for alternative approaches in this field. For the first time, the Information Day was available as a webcast for those who could not attend.

CAAT policy program information day in Chicago

On November 5, 2009 CAAT co-sponsored a program entitled "Implementation of the U.S. National Research Council Report on Toxicity Testing in the 21st Century: Can We Make the Business Case for Alternatives?" In addition to CAAT, program sponsors included, the Environmental Law Institute (http://www.eli.org/, Washington, DC), the Center for Animal Law Studies at Lewis & Clark Law School (http://www.lclark.edu/law/centers/animal_law_studies/, Portland, OR), the Animal Legal Defense Fund (http://www.aldf.org>, CA) and the Student Animal Legal Defense Fund at the University of Chicago Law (http://www.law.uchicago.edu/). This program was the third in a series of symposia focused on implementation of the US National Research Council's report *Toxicity Testing in the Twenty-First Century: A Vision and a Strategy*. Approximately 40 people attended the program, which was held at the University of Chicago School of Law. In addition to panelists from CAAT, speakers included representatives from the U.S. Environmental Protection Agency, PepsiCo, 3M, CeeTox, the Council of Canadian Academies, the Research Institute for Fragrance Materials, and the UC Davis Veterinary School.

Response to two Nature articles

Two Nature articles (Hartung, T., 2009, Toxicology for the Twenty-first century. *Nature 460*, 208-212, and Hartung, T. and Rovida, C., 2009, Chemical regulators have overreached. *Nature 460*, 1080-1081), and the underlying study, published in the last issue of ALTEX, have continued to stimulate discussion about the feasibility of REACH and the need for new approaches. German television (SWR 3) aired a further report on the subject. The current issue of ALTEX includes Hartung and Rovida's reply to the responses received from the European Chemical Agency and the US Environmental Defense Fund.

CAAT director joins ECOPA board

The European Consensus Platform for Alternative Methods is the umbrella organization for 16 national consensus platforms, each bringing together academia, industry, government, and animal welfare interests to promote alternative methods. On the occasion of their 10th anniversary meeting in November 2009, a new board was elected, chaired by Adela Lopez De Cerain (University of Navarra). As one of the newly elected ECOPA board member, CAAT director Thomas Hartung will work to ensure close collaboration between ECOPA and CAAT-EU.

Upcoming CAAT events

Please reserve the following dates:

- CAAT-EU inauguration with first European board meeting, to be held at the 30th March 2010
- CAAT policy program symposium end June 21-22, 2010 in Washington. An adjacent CAAT-US board meeting is also planned.
- CAAT-EU Information Day on US Toxicology in the 21st Century initiatives, Konstanz, Germany, June 2010
- CAAT Tox-21c Implementation conference (in collaboration with ACC and CropLife America), July 13-14, 2010, in Baltimore
- Conference with Physicians Committee for Responsible Medicine (PCRM), Washington fall 2010 "Animal Research and Alternatives: Measuring Progress 50 Years Later."
- IIVS Conference co-organized by CAAT, October 18-19, 2010 in Alexandria, VA

New publications

Basketter, D. A., Kimber, I. and Hartung, T. (2009). The evolution of validation: a commentary. *Cutaneous Ocular Toxicol.*, (in press).

Daneshian, M., von Aulock, S. and Hartung, T. (2009). Assessment of pyrogenic contaminations with the validated human whole blood assay. *Nature Protocols 12*, 1709-1721.

Ferrario, D., Collotta, A., Carfi, M. et al. (2009). Arsenic induces telomerase expression and maintains telomere length in human cord blood cells. *Toxicology 260*, 132-141.

Forti, E., Bulgheroni, A., Cetin, Y. et al. (2009). Characterisation of cadmium chloride induced molecular and functional alterations in bronchial epithelial cells. *Cell Physiol. Biochem.*, (in press).

Hartung, T. (2009). Per aspirin ad astra. *ATLA*, (in press).

Hartung, T. and Dasto, G. (2009). Are in vitro tests suitable for regulatory use? *Tox. Sci. 111*, 233-237.

A new web-portal to support non-animal research: InVitroJobs.com

The development of non-animal methods in research has advanced rapidly in recent years. The website InVitroJobs.com was created to support this important branch of science. Many researchers have a strong interest in animal-free research, but find information on research groups who use non-animal methods hard to come by. The aim of the portal is to enable scientists and young scholars to access this branch of research more easily.

Alongside the job search portal, an up-to-date *list of research groups* which are active in the development of non-animal research methods or mainly apply these methods is maintained. Here, students as well as established scientists will find an overview of the current research landscape. Contact information is provided in order to facilitate the search for a thesis assignment or internship or to establish contact to other research groups. This will help to expand networks and generate new ideas. The list is regularly updated and enlarged and groups interested in being listed are welcome to provide their information.

The website allows *posting vacancies free of charge* in the categories: a) Jobs b) Internships c) Thesis assignments. *Situations wanted advertisements* can also be posted free of charge.

The website offers a multiplicity of information: The "*News*" category supplies comprehensive information on current developments in research and politics. A *newsletter* providing regular updates on current developments in non-animal research is under construction. A *Literature survey* shows publications on specific topics. A *link list* to further information is maintained and a *survey of foundations and organisations* which support the development of non-animal methods by *grants and funding* is provided.

Exchange with competent interested parties is welcomed and advice and information about current methods in non-animal research is gladly provided.

The platform supports ethically defensible, modern and scientifically reasonable research.

InVitroJobs is a project of People for Animal Rights Germany (Menschen für Tierrechte - Bundesverband der Tierversuchsgegner e.V.) Contact: Telephone: +49 (0)731 17 67 285 info@invitrojobs.com