



Dear ecopa-messenger subscribers,

This is the third "ecopa messenger" edition in 2005.

And during the past 11 months, our *ecopa* website has become an even more important information tool for the alternative method development scene of the EU. We have had a total of 30017 hits, 8251 visits, by visitors out of 37 countries on average per month. You might have noticed that the alternative web approach "*ecopa.tsx.org*" is not available any more.

Details of the *ecopa*-activities and events, can be seen on the website: you will find the draft program of the [6th Annual ecopa Workshop on December 17.-18., 2005](#). It will be addressing:

"Nanotech, Biotech and other new technologies: safety testing and research requirements"

 [PDF: Registration form for the 6th Annual ecopa Workshop \(24 kb\)](#)

Depending upon the outcome of the actual REACH discussions and procedure in the Committees, European Parliament and Council, we will held our [EU Chemical Policy Workshop on REACH](#) one day before the *ecopa* Annual i.e. December 16th, 2005. It will be addressing the impact of the final REACH decisions on animal testing of chemicals and is titled:

**REALity CHECK: Proposals, Amendments and Conclusions -
from the alternative point of view**

(Please, stay tuned with our website, section EVENTS, whether the EU will have finalized their consultations before the set date of the Workshop, or whether we have to postpone into 2006)

And as usual, there are updates on the 6th EU projects that *ecopa* is participating in, such as ReProTect, PREDICTOMICS and Sens-it-iv. *ecopa* is now also involved in preparation of the Projects Lintop and Carcinogenomics

Any proposal or recommendation regarding style, content or distribution of the newsletter is highly welcome and appreciated (bgarthoff@t-online.de).

If you know other people or institutions interested, have them visit our website and subscribe to this newsletter.

Bernward Garthoff
Treasurer ecopa
on behalf of the ecopa
Management Board

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Issue # 05 (November 2005)

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**General News****Recent News on REACH**

Whereas the Committees responsible for REACH and respective rapporteurs (Guido Sacconi, of the Environment Committee, Lena Ek from the Industry Committee and Hartmut Nassauer from the Internal Market Committee) have finalized their discussions, the two largest parties (i.e. the EVP and the SPE) have agreed on a common line in expectation of the European Parliament voting on Thursday, November 17th.

The compromise is oriented along the lines of the British Presidency proposal.

The discussion and voting of the Council were supposed to take place by November 28th. The voting has been postponed, by the British Presidency on the proposal of the German government.

The EU Commission under lead of Commissioners Verheugen and Potocnik, has initiated a partnership program with the industry and industry associations resp. individual companies. A first kick off meeting was held on November 7th, 2005 – a follow up of this approach "Europe goes alternative" will be held each year; this will be done in kind of a workshop, assumed to happen in November each year.

http://europa.eu.int/comm/enterprise/events/animal_tests/conference/formreg.htm

As a follow up to the kick off meeting on November 7th, 2005 of the EU Commission / Industries-Partnership, the UK group ADI gave their point of view.

http://www.navs.org.uk/download_files/vivisection/reach_briefing.pdf

http://www.navs.org.uk/download_files/vivisection/acutetox_briefing.pdf

More EU REACH information for professional users

The European Agency for Safety and Health at Work has set up a website giving information on proposed regulatory reforms for professional users of chemicals. The site presents details on the proposed rules for the Registration, Evaluation, Authorization and Restrictions of Chemicals, which includes substances such as agrochemical intermediates and co-formulants.

More EU REACH information:

A group of European toxicologists have written [an open letter with attached documentation](#) to Commissioner Verheugen by mid of September (published in ENDS Environment Daily, issue 1938, September 12, 2005).

This Info-Service will also be organizing a REACH conference on December 5, 2005 under the headline "Implementing REACH " at the Crowne Plaza, Brussels.

www.endsreachconference.com

Also, The EU is not only in the process of developing and putting in place the new chemicals policy REACH, but it is planning to implement the globally harmonized system (GHS) for the classification and labeling of chemicals at the same time. The best current estimate is that REACH will come into force early in 2007. Clearly, the GHS is behind REACH in the regulatory process. The Commission has drafted much of the proposal to implement GHS and will meet key stakeholders in 2006 for public consultation. (ECN, October 24, 2005)

Other News

5th World Congress on Alternatives & Animal Use in the Life Sciences, Berlin, Germany, August 21-25, 2005 ([click here to download a ZIP-file with pictures from Berlin](#)):

ecopa was taking part with several presentations of their members in the World Congress, and was also present with an information booth in the exhibition area. We proposed also the presentation of one of the keynote-speakers, Prof. Eyzerik (who was one of our Senior Research Scientists participating in our eSI Workshop 2004

There is a new quarterly newsletter "Forward Focus", *A P&G Update on Innovation in Alternative Testing and Care* with the 2nd edition out now. It will be distributed via email and posted online at:
http://www.pg.com/science/animal_alt.jhtml.

Also, P&G has presented Awards for European Welfare and Alternatives over 25000 Euro each. Applications were due by August and application procedures are provided at
http://www.pg.com/science/animal_alt.jhtml.

The winners can be found under the following link: (for Alternatives) Prof. Vera Rogiers, (for Welfare) Prof. Jan Hauu. The Federation of European Toxicologists and European Societies of Toxicology (EUROTOX) and Humane Society International, in conjunction with P&G, presented the 2005 Animal Welfare and Alternatives Awards. Further Information on the recipients announced can be obtained by:
www.pg.com/science/awa_awards_intro.jhtml?CFID=260980&CFTOKEN=84273187

European Presidency

European Presidency is changing every 6 months. Next after the British Presidency ending in December 2005, will be Austria for the first half of 2006 and Finland for the second half of 2006. Starting 2007, the Presidency in the Council will be done by a group of 3 member states

First half of 2007 Germany
 Second half of 2007 Portugal

First half of 2008 Slovenia
 Second half of 2008 France

First half of 2009 Czech Republic
 Second half of 2009 Sweden

First half of 2010 Spain
 Second half of 2010 Belgium

First half of 2011 Hungary
 Second half of 2011 Poland

First half of 2012 Denmark
 Second half of 2012 Cyprus

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 **Statement regarding SCALE**

During the *ecopa* Annual Workshop 2004, the proposal of a new *ecopa* Statement regarding SCALE was agreed to. In the mean time, a lot of European citizens have signed our statement, but as this EU-programme is further to evolve, we ask you urgently to keep on undersigning. These will be used to document the will of European citizens to Commission and Parliament.

Please find the full text below and sign-in on our website:
[ecopa statement in regard to SCALE \(with sign-in\)](#).

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 **Technical Info to use the Forum of ecopa**

The Forum Section is now available via the *ecopa* page or the direct link:
<http://ecopa.vub.ac.be/forum/>

- In regard to EU Project/*ecopa* Working Groups:
to read and post messages in the Forum-section of the *ecopa* website, the users need to register themselves. After registration (and authorization by Board and Webmaster), each user-address has to be activated for this section.
- In regard to the General Discussion Section:
the users need to be registered to post messages in this section, but they can read all posts in here.
- The Forum itself is quite self-explanatory, here is just a short introduction and in addition you will find a detailed Q+A Section there as well: [\(forum FAQ\)](#)
- After you have registered yourself, click on a section to view or post a message.
- To post a message, click in a section on "new topic". When there already is a message in a section, you can click on "new reply" to directly reply to that message. You can click the button "pm" under a message, to write a private message to the author.
- Go to learn-by-doing, for any other questions or problems you can have a look at the forum-FAQ Section [\(forum FAQ\)](#) or send a mail to the Webmaster.

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 **Second update on the 7th Framework Programme**

Status September 2005

On September 21, the EU Commission proposed the draft for the specific programmes within the framework of the 7th FP.

1. Health (7.35 bn EUR): focus on "translational research", i. e. turning basic research into clinical applications respectively development and validation of new therapies
2. Food, Agriculture and Biotechnology (2.17 bn EUR): focus on healthier and qualitatively better food, sustainable production and usage of renewable bio-resources
3. Information and Communication Technologies
4. Nanosciences, Nanotechnologies, Materials and new product technologies
5. Energy
6. Environment
7. Transport (Aeronautics)

8. Socio-Economic Sciences and the Humanities

9. Security and Space

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Abstract of the project

The CONAM project is proposed by ecopa. This is the only quadripartite not-for-profit organisation that promotes a consensus strategy for 3R-alternative methods in the EU. Innovative is that the 4 parties having a major interest, animal welfare, industry, government and academia, are equally represented and reach consensus. Actually, national consensus platforms of 10 Member States, 2 Associate States and 2 Associate Candidate Countries are involved.

The objective of CONAM is to build a solid network on 3R-alternatives, ideally including all European countries and with the aim to deliver critical consensus expert opinions on 3R-issues, to draw attention on new alternatives and technologies, to disseminate this information and to initiate collaboration.

Identified priorities are:

- Consensus networking on 3R-alternatives with focus on website expansion, to support existing and new national consensus platforms, to stimulate collaboration and linking in particular with non-EU candidate countries.
- Ethics with emphasis on harmonisation and consensus by analysing and proclaiming shared ethical, legal and societal values, to continue dialogue where others failed and to develop consensus documents with focus on "omics" technology, access to human data and samples.
- Education activities to support (inter)national training and education of 3R-methods with focus on non-EU candidate countries.
- Legislative issues with emphasis on the EU Chemicals Policy: to harvest relevant information on the translation of the EU White Paper into legislation, to disseminate and discuss among the 4 parties, to come with a consensus paper to advice the EU decision making process. ecopas networking offers equilibrated, scientifically-sound and technically-relevant expertise and experience. The opportunities of emerging "omics" technologies should be fully explored, including ethical, educational and socio-political impact.

Recent News

ecopa representatives were asked to present at the 10th International Conference of Toxicology "Living in a Safe Chemical World" in Tampere Finland in July 11-15, 2004 on alternative development aspects. The respective publications have recently appeared in Toxicology and Applied Pharmacology. (207, Number 2, 2005, S 388 resp. S 408 !also available online at www.sciencedirect.com)

Representatives of ecopa in EU projects 6th Framework Programme:

BioSim – Flavia Zucco accepted the invitation to represent in the just started EU Project

Carcinogenomics – Arthur van Iersel will be named the ecopa representative in this new IP FP6 project

Acu Tox – Peter Maier is the representative in the Advisory Board

Sens-it-iv – Vera Rogiers is the representative in the Advisory Board

PREDICTOMICS – Bernward Garthoff is the representative in the Advisory Board

Lintop – Horst Spielmann will be the representative in the Advisory Board

ReProTect – Karin Gabrielson, Vera Rogiers and Bernward Garthoff (Chair) are representatives on the Supervising Board

Platforms

Austrian Platform ([z e t](#))

z e t – Austrian Centre for Alternative and Complementary Methods to Animal Testing

The Austrian Platform is currently preparing the program for its next alternatives meeting in Linz/Austria. It will be held from June 2 to 4, 2006. There is a session planned for 3 R-success stories, to be attended by participants of the new member states and the EU Commission.

Dutch Platform ([nca](#))

NCA - The Netherlands Centre Alternatives to Animal User

A report entitled "Regulatory Animal Testing" by Schiffelers et al. Utrecht University, has recently appeared. The study describes the factors and actors that influence the use of animal testing to comply with regulatory requirements. The study was conducted in the framework of the ZonMw "Limits to Animal Testing" programme. (available as a PDF doc at www.bio.uu.nl under 'publications')

Danish Platform

Most likely, the Danish Platform will be officially established before Christmas 2005. The name of the new association will be DACOPA- the Danish Ministry of Justice to be implementing it.)

Swiss Platform ([3R Research Foundation](#))

Update on Activities and the Annual Report:



[PDF: Short annual report 2005 of the 3R Research Switzerland \(76 kb\)](#)



[PDF: Annual Reportecopa 3R 2004 \(236 kb\)](#)

Finnish Platform (fincopa)

Fincopa, the Finnish national platform of ecopa was officially established in Tampere 21.09.2003, during the Scandinavian Workshop on In Vitro Toxicology, in a meeting of 10 Finnish participants representing academia, industry, animal welfare and government. In the meeting the goals of this Finnish national platform were defined and a draft of the rules of Fincopa was presented. Fincopa was registered as an official society in the Register of Foundations by the National Board of Patents and Registration of Finland 09.11.2004.

The number of members in November 2005: 31.

The members of board in 2005 (with personal deputy members):

Hanna Tähti (Sakari Alaranta), president

Eila Kaliste, secretary (Maria Anderson)

Marianna Norring (Riitta Salmi), treasurer

Risto Rydman (Paula Hirsjärvi)

Timo Ylikomi (Seppo Peuranen), deputy president

Christina Björklund (Juha Korpinen)

Hannele Huuskonen (Pia Korjus)

Kimmo Louekari (Outi Vainio)

Meetings

1. Board meetings

22.03.2005, Helsinki

03.11.2005, Helsinki
 2. Annual meeting
 20.05.2005, Turku

Participations in scientific and other meetings/activities:

Eila Kaliste and Marianna Norring: *ecopa*/CONAM Consensus Meeting 2005, June 9-12, Hotel Mons, Ljubljana, Slovenia

Hanna Tähti, Eila Kaliste, Marianna Norring, and several others: 5th World Congress on Alternatives & Animal Use in the Life Sciences, Berlin August 21-25 2005

Organisation of REACH seminar in Helsinki: 3.11.2005 together Finnish Laboratory Animal Science Association and Finnish Society of Toxicology: 63 participants Presentations: Hanna Tähti: In vitro -testien kehitystilanne vaihtoehtona toksikologiselle testaukselle (Situation of in vitro testing as an alternative to toxicologic testing); Kimmo Louekari: Pohjoismainen yhteistyö ja REACH (Nordic cooperation and REACH) Several members gave their opinions in their own organisations about the new national law for laboratory animal activities in year 2004. In 2005, the members were also consulted in the committees of Parliament during the reading of this law. Members participated in the preparation of the working group report 'Coordination of alternative methods for animal experiments in Finland', Ministry of Agriculture and Forestry.

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In future, the FORUM page for CONAM will also be activated, see above for technical details.

Also, the FORUM will contain the more general information available on the CONAM project, which will not necessarily be referred to by this newsletter so, check it out ([ecopa forum](#)).

As part of the CONAM project and in response to the request of the E U, we will give any news, minutes of project (as far as they are non-confidential and non-proprietary) or post relevant info in the respective Forum Section. We will refer to it by use of the Newsletter. Also, as part of *ecopa* extended mission, we will refer to up coming events such as local workshop, conferences, meetings of the NCPs or *ecopa* working group etc. on our Website [EVENT page](#), and if appropriate, in this newsletter.

Please supply us with the relevant info whenever deemed useful in your own interest.

Interested to form a new national platform in your country, if not existing?
 Please contact us under the [CONTACT page](#).

For an upfront info how to create a platform in your country, and which criteria apply to be official recognized by *ecopa*, refer to the presentation of JosŽ Castell at the Stakeholder Workshop in Prague ([ECVAM/ecopa Stakeholder Workshop](#))

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This 6th FP-project, that *ecopa* had co-initiated and in which *ecopa* is represented with 3 members in the Supervising Board including the Chairperson, was started in 2003 with 21 partners.

The overall funding is scheduled to be 9.1 mio EUR, resp. 13.5 mio EUR. Contract with the EU was signed on July 1, 2004; the administration is performed by Prof. Michael Schwarz, University of Tübingen.

Abstract of the Project

ReProTect is an Integrated Project of the EU (IP) funded within the 6th Framework Programme.

This Integrated Project, putting together 35 different European partners from Academia, SMEs, Governmental Institutes and others intends to explore the most complicate and delicate field of toxicology, the reproductive toxicity. The investigation in this field currently requires substantial number of animals and the main objective of this IP is to reduce this number. The project will drive the R&D toward alternatives to animal tests according to the needs identified, with the main intention to pre-validate and validate the most promising ones. This represents the ambition of developing a novel approach in hazard and risk assessment of reproductive toxicity, by a combination and application of in vitro, tissue and sensor technologies. The project will run over 5 years.

Recent News

Minutes of the 4th ReProTect Supervising Board Meeting
Tübingen, Germany, July 14, 2005

 [PDF: Minutes of the 4th ReProTect Supervising Board Meeting \(82 kb\)](#)

At present not available for the public!

[Pictures of the 4th ReProTect Supervising Board Meeting](#)

 [PDF: Minutes of the Teleconference of the ReProTect Supervisory Board Members \(67 kb\)](#)

At present not available for the public!

Next Date: Supervising Board Teleconference scheduled for midst of December 2005

For contact: reprotect@jrc.it

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PREDICTOMICS

The *ecopa*-induced 6th Framework Programme project has been started in 2003, with 14 partners, all in all. The overall funding is scheduled to be 2.3 mio EUR. Contract with the EU was signed on September 1, 2004; the administration is done by REMA.

Abstract of the project

The development of new pharmaceutical compounds will be more efficient if human relevant toxicology information early in the selection process is available. While acute toxicity can be reasonably detected during the early preclinical stages of drug development, long-term toxicity is more difficult to predict, relying almost exclusively on animal experiments. Animal experimentation of this kind is expensive and time consuming, raises ethical issues and does not necessarily represent best toxicological relevance to man. This project addresses the urgent need to develop in vitro based systems which are capable of predicting long term toxicity in humans.

The major objectives of this project are:

- 1) To develop advanced cell culture systems which as best possible represent the human liver and kidney in vivo. This will be achieved using combined strategies namely: co-cultures of resident cell types, targeted cell transformation, stem cell technology and new developments in organotypic cell culture (i.e. perfusion cultures and 3D cultures).
- 2) To identify specific early mechanistic markers of toxin induced cell alterations by using integrated genomic, proteomic and cytomic analysis.
- 3) To establish and prevalidate a screening platform (cell systems together with analysis tools) which is unambiguously predictive of toxin induced chronic renal and hepatic disease.

This proposal is unique in its mechanistic integration of the three levels of cellular dynamics (genome, proteome and cytome) together with advanced cell culture technology to detect early events of cellular injury. Only with such an integrated approach will in vitro techniques ever be

applicable to predicting chronic toxicity in man.

This project, if successful will (1) contribute to the replacement of animal testing in drug development, (2) increase the speed and decrease the cost of bringing new pharmaceutical compounds to the patient and (3) increase our understanding of toxin induced chronic disease development.

Recent News

The kick-off meeting was held on September 24 and 25, 2004 close to Valencia [Minutes of the Predictomics Kick-Off meeting](#)

The 2nd meeting was held near Innsbruck, Austria. This 1st Interim Meeting of the project PREDICTOMICS took place at the "Tiroler Bildungsinstitut" in Vill, near Innsbruck, during April 12-15, 2005, organised by Prof. Walter Pfaller and Dr. Paul Jennings, of the Innsbruck Medical University, Department of Physiology and Medical Physics.

After an initial reviewing of the milestones scheduled for the first six months of the Project done by the coordinator at the get-together meeting, the two subgroups "liver" and "kidney" met separately to analyse their respective work progress. Both groups examined in detail the strategies being employed to preserve the differentiated phenotype of cells in culture, and the developments in the "omics" technologies that will be applied to examine the effects elicited by chronic toxins. Attention was also devoted to discuss about the suitability of the model substances selected in this study, which comprise few representative chronic toxicants. The metabolic competence of kidney cells was an important issue raised during the common discussions that followed the two sub-groups meetings. A collaboration between the liver and kidney groups was planned to characterise the kidney cells used in this project (RNA, protein and activity measurements), and to compare with human kidney extracts and/or freshly isolated kidney cells.

The follow-up meeting discussing the 1st Annual Report took place in the Netherlands in September 2005, Report to follow with the next *ecopa* messenger.

The non-confidential information on the First Annual Report of the PREDICTOMICS project [can be found as a Publishable Executive Summary here](#).

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Abstract of the project

The eSI Conference under the heading: "Reaching the young scientist" was an initiative organised by ecopa aimed at bringing together senior as well as young researchers to discuss about the new technologies and their applicability in in vitro research as well as to improve creativity and innovation in the search for alternative methods. ecopa had performed a detailed literature analysis of the last 5 years of research in alternative methods and had concluded that this area of applied research is drying out.

ecopa had invited some renowned European scientists, i.e. "doyens" in their field of research such as proteomics, genomics, pharmaco- and toxicogenomics, but also of other areas that might have relevance to the development of alternative methods. It was not asked for immediate proposals for alternatives application from these key note speakers in their state of the art-presentation, but this had to be back in their mind, of course. In addition, ecopa has asked experts of technology applications to give their input as well. Also, ecopa invited some young research scientists and postdocs who might have some application for their current reseach projects.

The Workshop took place with 52 participants representing 14 European countries, 6 companies, thereof 1 SME.

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EU 6th Framework Programme Projects / ecopa Working Groups

Details, Minutes, Contract numbers and alike will be dispatched on the FORUM pages in future, once activated by the individual teams.

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Allergies to sensitising agents are steadily increasing. Risk assessment for potential skin- or lungsensitisers, completely depends on animal testing. The overall objective of Sens-it-iv is to produce in vitro alternatives for these assays, and develop them up to the level of pre-validation. Besides reducing animal experimentation, an increase the accuracy of predicting sensitising potencies is expected.

In vitro mechanisms, relevant for in vivo sensitisation, will be identified at the level of human lung or skin epithelial cells (EC), dendritic cells (DC) and T-cells. These efforts imply specific scientific (S) and technologic (T) objectives:

Abstract of the project

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- Existing data on sensitising, irritating and toxic compounds are collected (S).
- In vivo changes induced by selected compounds in the specified cell types are described using functional genomics (S).
- Similarly, the impact of compounds on individual cells, and the interaction between these cells is assessed in vitro (S).
- The physico-chemical properties of chemicals responsible for metabolic activation and hapten-formation are determined (S).
- The data are collected in an Inductive Database allowing queries for data patterns and predictive models (T).
- Mechanisms specifically involved in skin and respiratory sensitisation are identified using bio-informatics (S).
- The information is used to adapt/improve existing techniques, and to develop organotypic models derived from human cells assays (T).
- A proof of principle is established on a set of selected skin and respiratory sensitisers, irritants and toxic compounds (T).

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Other Projects / Calls

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 **Nanotech EU-Consultation**

The European Commissions has launched a public consultation on risk assessment methods for nanotechnologies. The aim is to gather feedback on current methods of assessing the risks and how to improve them, rather than on the risks of nanotechnologies themselves.

"Unquestionably, consumer safety remains the first and highest priority", said European Union commissioner for health and consumer protection, Markos Kyprianou. Nevertheless, he noted: "We must avoid a situation where the marketing of highly innovative nanotechnology products by difficulties providing consumers with the safety assurances they seek."

Stakeholders are asked to respond online by December 16th.

Opinion and consultation:

http://europa.eu.int/comm/health/ph_risk/committees/04_scenihhr/scenihhr_cons_01_en.htm

ecopa will address nanotech in its Annual Workshop on December 17th, 2005.

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BioSim

BioSim, or "Biosimulation – A New Tool in Drug Development" started December 1, 2004. BioSim is a Network of Excellence supported by the European Commission as part of its 6th Framework Programme.

BioSim aims at contributing to the fulfillment and to the establishment of the 3R- Declaration. The purpose of the Network is to illustrate how the use of professional, physiologically based simulation models can help the pharmaceutical industry develop safe and effective drugs at significantly lower costs and with fewer animal and human trials.

The idea is that computer simulation should go hand in hand with the trials throughout the whole development process. This represents a more rational approach than a purely empirical test procedure.

2005 Humane Education Award for alternatives in education

InterNICHE announces the 2005 Humane Education Award for alternatives in education. 20,000 Euro (US\$ 25,000) is available to be split between successful proposals.

Proposals are invited from all countries for initiatives to replace animal use in biological science, medical and veterinary medical education. Applicants may be individuals committed to enhancing the efficacy and ethics of life science education.

The deadline for applications is 25th November 2005.

Applications must be submitted through the on-line form at

<http://www.interniche.org/award/2005award.htm>

Attachments may be sent separately to coordinator@interniche.org.

2006 Animal Welfare Enhancement Awards

<http://caat.jhsph.edu/programs/AWE/call.htm>

Attention lab technicians, animal technicians, and all who work with laboratory animals: The Johns Hopkins Center for Alternatives to Animal Testing (CAAT) now is accepting proposals for the 2006 Animal Welfare Enhancement Awards.

Deadline for submissions is December 1st, 2006.

Upcoming Symposium

TestSmart DNT: Creating a Humane and Efficient Approach to Developmental Neurotoxicity Testing March 13-15, 2006

Register Now! <http://caat.jhsph.edu/dnt/index.htm>

The forthcoming IVTS meeting on the theme of "Understanding Mechanisms of Toxicity: In Vitro Research and Industrial Applications" to be held at the University of London on 1st December. To allow for additional registrations, we have extended the registration deadline to Friday 18th November. Visit the IVTS website at: <http://www.ivts.org.uk>

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