



2006-07-05, edition #08-2006

**Dear ecopa messenger subscriber,**

This is the second "ecopa messenger" edition in 2006, and it contains an update on our EU Chemical Policy Workshop on REACH detailing the impact of the REACH proposals on animal testing of chemicals under "REALity CHeck: Proposals, Amendments and Conclusions - from the alternative point of view".

This *ecopa messenger* summarizes the results of the REACH impact workshop of Feb.1, 2006. All presentations can be found under the link below, and will form the basis for the consensus report on the potential "impact of REACH" to be finalized by the CONAM Chemical Policy Working Group in late 2006. Assumption is that final regulations are presented to the EC public by then.

» [Presentations of the ecopa Annual Workshop](#)

» [Photos of the ecopa Annual Workshop](#)

Participants had received a free copy of the "animal test calculator" prepared by our Chemical Policies Working Group which also will be used as a tool for the final REACH impact studies and analysis.

The CONAM/*ecopa*-Board Meeting on March 15/16, 2006 in Basle/CH has addressed the CONAM/*ecopa*-Status and planning for the events of 2006 and beyond - see the minutes:

 [PDF: Minutes of the CONAM WP leader meeting \(64 kb\)](#)

And as usual, there are updates in this newsletter on the 6th EU Framework Programme projects that *ecopa* is participating in, such as ReProTect, PREDICTOMICS and Sens-it-iv, Liintop, CARCINOGENOMICS and Bio-Sim. The new project CARCINOGENOMICS has been approved by the DG Research unit, contracts still in the making for a July start. Actually, there has taken place a summarizing workshop organized by DG Research covering all the projects funded within Framework Programme 6 on June 13, 2006, under the heading "EU-funded research on alternatives to animal experimentation: stocktaking from FP6 and views for the future". [The presentations given by the project coordinators](#) can be seen under the diverse project names and "Additional Projects" (i.e. Memtrans, BBMO, NHR Dev Tox, Vitrocellomics, TOXDROP, Rethink, Rainbow).

Also, there is information given on the [EU partnership EPAA](#) and the first 7th Framework Programme Technology Platform SusChem.


» <http://www.suschem.org/media.php?mId=4727>

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

Bernward Garthoff  
Treasurer *ecopa*  
on behalf of the *ecopa* Management Board

P.S.: If you know other people or institutions interested, have them visit our website and [subscribe to this newsletter](#).

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## **General News**

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### **Recent News on REACH**

After the discussions of the European Parliament, the EU Councils and two readings, process proceeds to reach a common joint draft of these institutions by autumn (2nd reading by September expected) up to the end of 2006, so that REACH can become effective by beginning of 2007. At that point in time, the final impact on animal testing and alternative method development can be estimated. Therefore, *ecopa* and its WG will give their final comments around that time and a first view at its Annual Meeting in November. EP rapporteur Sacconi had recently indicated that he wants to further foster the replacement of animal testing in the REACH programme.

*ecopa* had developed the "impact" software "REACH Animal Use Calculator" for free. The software allows anybody to calculate the impact REACH has on chemical testing requirements and on resulting animal numbers. All scenarios current and existing in future, can be modeled with it - it is also downloadable from our website.

 [XLS: REACH Animal Use Calculator \(572 kb\)](#)

 [PDF: Exercise proposals for the calculator \(40 kb\)](#)

Timing schedule:

First exchange of views in the leading Environment Council was on June 21, 2006. Deadline for amendments: September 11, 2006.

Vote in Environment Council by October 10, 2006, followed by the vote in the European Parliament Plenary, most likely be end of November 2006.

While the regulatory and legislative procedures at the EU Commission and in the EU-MSs are being set up, the preparations of institutions and industries are proceeding.

Trade associations such as CEFIC, UIC of France or the CIA of UK have set up companies (e.g. REACH Ready, [www.reachready.co.uk](http://www.reachready.co.uk), REACH Centrum) or institutes to deal with the complex process.

The European Commission has, as part of its preparations for REACH, started seven REACH Implementation Projects (RIPs):

**RIP 1:** REACH Process Description (e.g. an overview of REACH procedures)

**RIP 2:** REACH-IT (e.g. development of the hardware and software needed to support the collection and processing of REACH generated information)

**RIP 3:** Technical Guidance Documents for Industry (e.g. guidance on completing registrations, performing chemical safety assessments, managing data sharing, specifying requirements for articles)

**RIP 4:** Guidance Documents for Regulatory Authorities (e.g. guidance on performing evaluations, authorisation and restriction processes)

**RIP 5 & 6:** Setting-up the European Chemicals Agency and pre-Agency

**RIP 7:** Commission preparation for REACH

Further information on the RIPs is available via the European Chemicals Bureau website.

» <http://ecb.jrc.it/>

By May 5, the rapporteur of the EU Parliament, Guido Sacconi had released a working document in preparation of the 2nd reading.

» [http://www.smallbusiness europe.org/en/upload/File/Issues/REACH/Working\\_doc\\_2\\_reading.pdf](http://www.smallbusiness europe.org/en/upload/File/Issues/REACH/Working_doc_2_reading.pdf)

During these preparations, the political battle still goes on, between environmentalist organisations and industries (see ICIS, May 8, 2006, p.4) on the one hand, and also Commission on the other (see ICIS, May 5, 2006, p. 31).

In a speech the week before last week (week 24) to the European Parliament Verheugen said: "It is a balanced compromise which also takes account of the parliaments' concerns at the first reading and is the product of a very difficult process of negotiation. We should take this into account in the 2nd reading, in particular with regard to the rules on registration and approval. At the same time, I acknowledge, of course, that some proposals for amendments which met with broad support in the first reading should be taken into account. ... If the procedure could be completed in the 2nd reading, it would help us on implementing REACH rapidly." (ICIS, June 19, 2006, p. 40)

The establishment of the EU's planned new Chemicals Agency in Finland/Helsinki seems to have some "rocky" start-up; the agency has to have IT-systems in place by mid 2008, in order to handle registrations. Project Manager is the Finnish Jukka Malin.

Chemical companies have to prepare for the pre-registration period of 18 months starting most likely in the first half of 2007, with the final REACH-implementation. Producers and traders do have 12 months to identify the substances (up to 30,000) to be registered under REACH.

The European Parliament Committee on Development has meanwhile published a report on the "Implications of REACH for Developing Countries" quoted to be only "of marginal impact", whereas a report by the Sweden-based ChemSec indicates that also the US expects REACH to perhaps become the de facto global standard for regulating chemicals.

### **More EU REACH information Partnership on Alternative Approaches to Animal Testing (EPAA)**

The EU Commission under lead of Commissioners Verheugen and Potocnik, had 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 on this approach "Europe goes alternative" will be held each year; this will be done in kind of a workshop, assumed to happen at the end of this year, in December. The EPAA has agreed for 21 activities to be carried out over the next 5 years.

The partnership thereby has finalized the development of the program, all the details known until now are on the website.

 [PDF: EPAA Action Programme \(140 kb\)](#)

» [http://ec.europa.eu/enterprise/epaa/index\\_en.htm](http://ec.europa.eu/enterprise/epaa/index_en.htm)

» <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/814&type=HTML&aged=0>

» <http://europa.eu.int/rapid/searchResultAction.do?search=OK&query=Indus&username=PROF>

Colin Humphries, executive director of CEFIC and co-chair of EPAA, indicated that there will be a mirror group of stakeholders including animal welfare bodies and patient groups that will have input into the process.

### **EU-Community Action Plan**

Also, the EU Commission has released a Working Document and a Communication to the Parliament and Council as the basis of a "Community Action Plan on the Protection and Welfare of Animals, 2006-2010".

 [PDF: Community Action Plan \(131 kb\)](#)

 [PDF: Commission Working Document \(218 kb\)](#)

## EU-Consultation Process

The EU has started a stakeholder consultation in an effort increasing the welfare of animals used in experiments: Public consultation on the revision of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purpose.

The closing date is August 18, 2006.

» [http://ec.europa.eu/environment/chemicals/lab\\_animals/ia\\_info\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/ia_info_en.htm)

## GHS (Globally Harmonized System)

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 though the first version is around since 2003, after 10 years of preparation. The Commission has drafted much of the proposal to implement GHS and will meet key stakeholders in 2006 for an abbreviated public consultation.

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## Other News \* top

### Nanotech

In following-up our well-received workshop on "Nanotech, Biotech and other new technologies" at the last Annual *ecopa*-Meeting in December 2005, we would like to draw your attention to recent statements, workshops and data banks that might be of interest for people in the field. The UK's Royal Society and Royal Academy of Engineering have called "for industry to put the methods they use to test the safety of products containing free nanoparticles ... into the public domain because this is one particular area where there is some uncertainty about safety." OECD released findings from a workshop on the safety of manufactured nanomaterials. (ICIS, May 15, 2006, p. 30).

 [PDF: Minutes of the 6th Annual \*ecopa\* Meeting \(163 kb\)](#)

### European Presidency

European Presidency is changing every 6 months. Next after the Austrian Presidency ending in June 2006, will be 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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## Technical Info to use the Forum of *ecopa* \* top

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](#))
- When you have registered, 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.
- Start learning 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.



## Third update on the 7th Framework Programme

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Status: Mid of 2006

On September 21, 2005, the EU Commission had proposed the draft for the specific programmes within the framework of the 7th FP. The European Parliament started its debate on the 7th FP by January 30, 2006. After some cuts, the major part has been agreed on in the EU Commission by May 29, 2006, resp. in the EP on June 15, 2006. An increase has been consented, also the new institution of a Research Council was accepted. All in all, funding of 54 billion € which correlates to a 60%-increase over FP6.

1. Health: focus on "translational research", i. e. turning basic research into clinical applications respectively development and validation of new therapies
2. Food, Agriculture and Biotechnology: 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

The Commission and the EP look for the Finnish presidency to implement, start is supposed to be by November 2006. *ecopa* will participate in the technology platform SusChem. See there.



## EU 6th Framework Programme Projects / *ecopa* Working Groups

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

### NOTICE:

To avoid misunderstandings and because of inquiries at the *ecopa* Annual Meeting December 2005 - please, be informed and take note that the following abstracts of the EU 6th FP Projects are original abstracts of the project proposals submitted to the EU Commission in most cases, and are not supposed to be adapted after the final contract agreements. Therefore, they will remain and read in their initial form.



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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. *ecopa*s 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

Representatives of *ecopa* in EU projects 6th Framework Programme:

- *BioSim* – Flavia Zucco accepted the invitation to represent in the just started EU Project
- *CARCINOGENOMICS* – A further person will be named the *ecopa* representative in this upcoming IP FP6 project
- *ACute Tox* – Peter Maier is the representative in the Advisory Board.
- *Sens-it-iv* – Vera Rogiers is the representative in the Advisory Board, and *ecopa* is seconding in the dissemination of results
- *PREDICTOMICS* – Bernward Garthoff is the representative in the Advisory Board
- *Liintop* – Horst Spielmann is the representative in the Advisory Board
- *ReProTect* –Karin Gabrielson, Vera Rogiers and Bernward Garthoff (Chair) are representatives on the Supervising Board, and *ecopa* is seconding in the dissemination of results
- *CARCINOGENOMICS* –*ecopa* has taken over the Work Package of dissemination of results of the consortium.



[PDF: CONAM - Minutes of the CONAM WP-Leader Meeting, March 16, 2006, Basle \(188 kb\)](#)



[PDF: CONAM Project \(56 kb\)](#)



[PDF: CONAM Specific Support Action \(236 kb\)](#)

Next CONAM Review Board Meeting will take place October 12th, 2006 in Paris.

## Platforms

### Austrian Platform

» [z e t – Austrian Centre for Alternative and Complementary Methods to Animal Testing](#)

- The Austrian Platform has supported the organization of the MEGAT Workshop in Linz/Austria. See the link for abstracts.

### Spanish Platform

» [REMA – Red Española de Métodos Alternativos](#)

 [PDF: NCP Spain - Activity Report 2005 \(168 kb\)](#)

### **Dutch Platform**

» [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](http://www.bio.uu.nl) under "publications")

### **Danish Platform**

» DACOPA

- According to message of the Danish Government, DACOPA has been officially established and the members are appointed. Ove Svendsen has been appointed as the chairman of DACOPA by the Minister of Justice for the next 4 years.  
CONGRATULATIONS!

### **Swiss Platform**

» [3R Research Foundation Switzerland](#)

- 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.

### **German Platform**

» [set](#)

- The Annual Report for 2005 has been published.



[PDF: set Activity Report \(76 kb\)](#)

### **UK Platform**

» [The Boyd Group](#)

- The Boyd Group was founded in 1992 as a forum for dialogue on contentious issues related to the use of animals in science. Its aims are to encourage productive debate about animal experimentation and alternatives, in order to clarify key issues of concern, work towards consensus where possible, make practical recommendations towards achieving common goals, and inform a wider public. The Group currently has more than 40 participants, representing a wide range of stakeholders, including veterinarians, scientists using animals (from industry and academia), members of animal welfare organisations, anti-vivisectionists, members of government and charitable bodies funding or directly engaged in research, philosophers and others. Further information and reports are available at the Group's web-site:  
» <http://www.boyd-group.demon.co.uk>

### **Polish Platform**

» [polcopa](#)

- The Polcopa Founding Committee was finally established.
- NCAM created a draft Polcopa web site (» [www.imp.lodz.pl/polcopa](http://www.imp.lodz.pl/polcopa)) in polish version. This site will be continuously updated as well as transformed into English version.



## Norwegian Platform

- The developing Norwegian Platform has performed a study on National Consensus Platforms in general.

 [PDF: Study Of The Norwegian School For Veterinary Science \(220 kb\)](#)

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 (» [events section](#)), 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 (» [contact section](#)).

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 Jose 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

Call for new partners in the ReProTect project, [please see under Calls](#).

 [PDF: Minutes of the 4th ReProTect Supervising Board Meeting, Dec. 15 2005 \(82 kb\)](#)  
*At present not available for the public!*

 [PDF: Minutes of the Teleconference of the ReProTect Supervisory Board Members, Jan 23 2006 \(67 kb\)](#)  
*At present not available for the public!*

 [PDF: Position Paper "ReProTect" \(103 kb\)](#)  
*At present not available for the public!*

Next Supervising Board Meeting is scheduled for July 5, 2006 in Uppsala, Sweden.

 [PDF: ReProTect - Publishable executive summary \(384 kb\)](#)



For contact: [reprotect@irc.it](mailto:reprotect@irc.it)



[PDF: ReProTect - Integrated Project \(302 kb\)](#)



[PDF: ReProTect - Estimated Testing Costs Of REACH \(128 kb\)](#)

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## PREDICTOMICS

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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

Find the non-confidential information on the First Annual Report of the PREDICTOMICS project here:

» [Publishable Executive Summary](#)

The 3rd meeting of PREDICTOMICS was held on 21-23 February 2006, and was hosted by Prof. Vera Rogiers at the Vrije Universiteit Brussels. The meeting was attended by all but one partners, including the representatives of ECVAM (Dr. P. Prieto) and *ecopa* (Dr. B. Garthoff). During the two-days meeting, different issues of the project were reviewed by participants. A thorough examination of the achievements of the past six months was done by both subgroups, and the deviations from the initial working plan were analyzed and discussed together. No major deviations are expected from the envisaged working plan in the forthcoming 6 months. Considerable scientific knowledge was brought by the partners involved in Kidney and Liver research, concerning the performance of the various cellular models and their suitability to meet the assay criteria defined in PREDICTOMICS. Based on the knowledge gained in the past 18 months, the Kidney and the Liver groups discussed in detail the pros et contras of the various cellular models to be used in the drug screening phase of PREDICTOMICS (3rd year). A final decision is to be adopted within the next six months.

The consortium has launched a new web with several improvements to facilitate the dissemination of the research done. In the public accessible part, clear and easy to understand information is provided

to a general reader, as well links to contact the individual groups through the webmaster. The next meeting will take place on 20 and 21 of September 2006, and will be hosted by Dr. Patrick Maurel in Montpellier (F). The meeting will allow to discuss and approve the 2nd Year Report to be submitted to the Commission.

Websites: [www.predictomics.com](http://www.predictomics.com) or [www.predictomics.org](http://www.predictomics.org)



[PDF: PREDICTOMICS - Specific Target Research Project \(268 kb\)](#)



[PDF: PREDICTOMICS - Short-term in-vitro assays for long term toxicity \(392 kb\)](#)



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[PDF: ACuteTox Summary Report \(80 kb\)](#)



[PDF: ACuteTox - Optimisation and pre-validation of an in vitro test strategy \(44 kb\)](#)



[PDF: ACuteTox - Integrated Project \(324 kb\)](#)



[PDF: ACuteTox - Integrated Project \(136 kb\)](#)

Website: [www.acutetox.org](http://www.acutetox.org)



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### Abstract of the project

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 of 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:

- 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 haptentformation 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).

### Recent News

CONAM / *ecopa* has taken over the responsibility "spreading the news/results" of this EU project, and just released a brochure covering the activities on behalf of Sens-it-iv, and supported the website creation.

Website: [www.sens-it-iv.com](http://www.sens-it-iv.com)

 [PDF: Sens-it-iv - Integrated Project \(336 kb\)](#)

 [PDF: Sens-It-Iv - Novel Testing Strategies \(244 kb\)](#)



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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.

### Recent News

Biosimulation - a New Tool in Drug Development. (BioSim) is a Network of Excellence financed by the European Commission under the VIFP.

It involves 26 academic research groups, 9 small and medium sized enterprises, Novo Nordisk, and the regulatory authorities in Sweden, Spain, Netherlands and Denmark.

The purpose of the NOE is to develop mathematical models that can contribute to a better understanding of human physiological and pathological processes and gradually provide the basis for a more rational drug development process.

Application of computer simulation in the drug development process can reduce the use of laboratory animal significantly through a more rational exploitation of the information acquired in each test and through a better planning of the experiments.

At this conference, among others, have been presented models of glucose-insulin control system, of cardiac arrhythmia, of biochemical reactions, of drug administration and circadian cycle, of hypertension and nephron interaction.

Objectives:

- Establish how biosimulation can contribute to the implementation of the 3Rs in animal and human research
- Establish if and how the 3Rs principle in animal research can be expanded to experiments on humans
- Increase the awareness among European research groups involved in biosimulation of the principle of the 3Rs in animal research
- Increase the awareness among European research groups involved in alternative methods research of the potentialities of biosimulation

For more information the home page of the project is the following:

» [www.biosim-network.net](http://www.biosim-network.net)



**Liintop**

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*ecopa* - Representative in Liintop is Horst Spielmann.

 [PDF: Liintop Summary \(22 kb\)](#)



## Additional Projects

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### Memtrans



[PDF: Memtrans - Specific Targeted Research Project.gif \(244 kb\)](#)



[PDF: Proposal: Membrane transporters \(484 kb\)](#)

### BBMO



[PDF: A Specific Strategic Action in the 6th Framework \(996 kb\)](#)



[PDF: BBMO - Specific Support Action \(304 kb\)](#)

### NHR DevTox



[PDF: Nuclear Hormone Receptors \(144 kb\)](#)



[PDF: DevTox - Integrated Project \(244 kb\)](#)

### Vitrocellomics



[PDF: Vitrocellomics - Integrated Project \(264 kb\)](#)



[PDF: Vitrocellomics - Reducing Animal Experimentation \(528 kb\)](#)

### TOXDROP



[PDF: REACH: TOXDROP Challenge \(244 kb\)](#)



[PDF: TOXDROP - Integrated Project \(1\) \(336 kb\)](#)



[PDF: TOXDROP - Integrated Project \(2\) \(100 kb\)](#)

### Rethink



[PDF: Rethink Project \(84 kb\)](#)



[PDF: Rethink - Integrated Project \(284 kb\)](#)

### Rainbow



[PDF: Rainbow Workshop \(232 kb\)](#)



[PDF: Rainbow - Specific Support Action \(284 kb\)](#)



## EU 7th Framework Programme Projects / preparation: SusChem

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### Sustainable Chemistry

The Technology Platform SusChem has been formed and finalized its Implementation Action Plan. It will be presented by July 7, 2006 on their website.

Their 4th stakeholder event will take place in Budapest, August 27, 2006 in connection with the 1st

European Chemistry Congress to discuss the Implementation Action Plan.

ecopa will be participating in the Horizontal Issues Group.

» <http://www.suschem.org/media.php?mId=4727>

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## Other Projects / Calls / Conferences

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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 research projects.

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

### Recent News

The next eSI Workshop will be held September 29 - 30 2006 at Pueblo Acantilado near Alicante, Spain. The preliminary program can be found in the minutes of the [CONAM Workpackage Leaders Meeting](#), and all National Platforms are requested to make proposals for senior research scientists or young researchers to participate and present there. Deadline : by July 15, 2006."

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### InterNICHE book on-line

Free download of InterNICHE book "From Guinea Pig to Computer Mouse: Alternative Methods for a Humane Education" (2nd ed.).

The publication "From Guinea Pig to Computer Mouse" (2nd ed.) is now available for free download as a pdf document. First published in 2003, with minor updates made in February 2006, the 520-page book provides full details of over 500 alternatives, including description, specification and source. It also offers background information on the diversity of alternative tools and approaches, a review of published studies that assess alternatives through learning performance, and an exploration of curricular design. The book provides links to over 600 further resources.

Texts from the InterNICHE book 'from Guinea Pig to Computer Mouse' (2nd ed.) are launched now online as well in Arabic, French, German, Korean, Polish, Portuguese, Russian and Spanish. The book is targeted at teachers and students of medicine, veterinary medicine and biology, and at ethics committees and animal protection groups. Each translation begins with a highly detailed introduction to different types of alternative to harmful animal use in education such as multimedia software and virtual reality, training mannequins and simulators, ethically-sourced animal cadavers, student self- experimentation and clinical work with animal patients.

See News at the InterNICHE website for links to the download page:

» <http://www.interniche.org>

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### 2006 Animal Welfare Enhancement Awards

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.

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

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### **2006 Eurotox/HIS/P&G Awards**

The awards for the Eurotox Procter&Gamble award programme are published on the website:

» [http://pg.com/science/animal\\_alt.ihtml](http://pg.com/science/animal_alt.ihtml)

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### **2006 European Animal Welfare and Alternatives Awards**

Applications are now being accepted for the 2006 European Animal Welfare and Alternatives Awards. There are awards of 25,000 Euros in the following categories: Alternatives, Welfare and Local Community Initiative.

The three awards are funded by Procter & Gamble (P&G). Recipient selection will be undertaken by a panel nominated by the Federation of European Toxicologists and European Societies of Toxicology (EUROTOX), the Humane Society International (HSI) and P&G. Applications are due by 11 August 2006.

» <http://www.nc3rs.org.uk/news.asp?id=250>

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### **2006 Intervet - Dieter Lütticken Award**

For those interested please refer to the link of the press release "Intervet Dieter Lütticken Award - Intervet's award to reduce the number of animals used in testing for development and production of animal veterinary medicines".



[PDF: Intervet - Dieter Lütticken Award \(84 kb\)](#)

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### **Eurca coordinator Prof. Dr. David Dewhurst received the Doerenkamp Zbinden Award 2006**

The Foundation Board of the Doerenkamp-Zbinden Foundation has unanimously decided to bestow the Doerenkamp-Zbinden Prize 2006 on Professor Dr. David Dewhurst from the University of Edinburgh. He received the Prize during the 13th Congress on Alternatives to Animal Testing in Linz, Austria (June 2-4 2006).

David Dewhurst received the Prize for his outstanding contributions to the replacement of animals in teaching of physiology and pharmacology.

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### **JRC, Call for Expression of Interest**

Validation of alternative test methods - call for expressions of interest

The Institute for Health and Consumer Protection of the European Commission's Joint Research Centre (JRC) has launched a call for expressions of interest for the validation of alternative test methods.

This call for expression of interest shall be divided into the following 20 sub-fields. Expressions of interest are invited for all or some of the following fields (sub-list):

1. systemic toxicity;
2. topical toxicity;
3. sensitisation;
4. carcinogenicity/genotoxicity;
5. reproductive toxicity;
6. pharmaco- and toxicokinetics;
7. ecotoxicology;
8. computational toxicology;
9. toxicology of nanoparticles;
10. biostatistics and bioinformatics;
11. food safety;

12. biologicals;
13. pharmaceuticals;
14. good laboratory practice;
15. good cell culture practice;
16. omics technologies;
17. robotised testing for cell and tissue culture application;
18. endpoint detection technologies for cell and tissue culture applications;
19. Correlate: reference laboratory for alternative testing methods, including assessment of equivalence, test substances evaluations, comparative studies and monitoring;
20. agrochemicals.

To see the full details of the call, please consult the following web address:

» <http://ted.publications.eu.int/udl?REQUEST=Seek-Deliver&LANGUAGE=en&DOCID=047741-2006>

The **deadline** for submitting tender documents is 24.11.2008.

Document Reference: OJ No S 46-047741 of 8.3.200

RCN: 25319

## **ESF/European Science Foundation, Calls 2006**

### **EUROCORES (European Science Foundation Collaborative Research)**

The scheme provides a framework to bring together national research funding organisations to support European research.

» [http://www.esf.org/esf\\_activity\\_home.php?language=0&domain=0&activity=7](http://www.esf.org/esf_activity_home.php?language=0&domain=0&activity=7)

### **Contact Dermatitis 2006: Blending Science with Best Practice**

September 28-30, 2006

Marriott Waterfront Hotel / Baltimore, MD

The goal of this meeting is to discuss the basic and applied science of contact dermatitis. Scientific exchange is fostered among scientists and dermatologists from academia, government, and industry working in the field of contact dermatitis.

» <http://www.cdc.gov/niosh/topics/skin/CD2006/index.html>

### **Practical Training Course on Alternative Test Methods in Topical Toxicity, Freie Universität Berlin, Germany**

» <http://userpage.fu-berlin.de/~invitrot/>

### **INVITOX 2006**

#### **14th International Workshop on In Vitro Toxicology**

October 2-5, 2006 - Ostend, Belgium

» <http://www.invitox2006.org/>

Cambridge Healthtech Institute's Third Annual

#### **CELL-BASED ASSAYS FOR HTS** – CD available:

Cell-Based Assays for HTS CD (Price: \$250)

» <http://www.WorldPharmaCongress.com/>

Enabling Targeted Therapies & Non-Invasive Imaging:

#### **Global Digital Healthcare** (October 10-11)

#### **AND Targeted Nanodelivery** (October 12-13)

» <http://www.healthtech.com/2006/nno/>

» <http://www.healthtech.com/2006/nno/req.asp>

Cambridge Healthtech Institute's Fourth Annual

#### **Target Discovery & Target Validation Strategies**, October 23- 27, 2006

World Trade Center, Boston, MA

» <http://www.discoveryontarget.com/>

### **EUROTOX 2006/6 CTDC Congress**

Dubrovnik/Cavtat, Hotel Croatia, September 20 - 24, 2006

» <http://www.eurotox2006-6ctdc.org>



» <http://www.eurotox2006.org>

**GD REACH Symposium, Berlin, Oct. 12, 2006**

Addressing implementation of REACH, organised by the German Society for Dermopharmacy (GD) and the German Federal Institute for Risk Assessment (BfR).

» <http://www.gd-online.de/german/veranstalt/images2006/REACH-Symposium-12.10.2006-Anmeldebogen.pdf>

**ESAC validity statements**

The ECVAM SCIENTIFIC ADVISORY COMMITTEE (ESAC) has made the following validity statements under the following links:



[PDF: ESAC - Statement \(1\) \(116 kb\)](#)



[PDF: ESAC - Statement \(2\) \(96 kb\)](#)



[PDF: ESAC - Statement \(3\) \(92 kb\)](#)

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