ecopa messenger

Dear *ecopa*-messenger subscribers,

This is the fourth "ecopa messenger" edition in 2005, and it gives a short update on our 6th Annual *ecopa* Meeting, more to come in the next edition. Further details of the upcoming *ecopa* -activities and events in 2006 can be seen on the website resp. via the link below in regard to time line!

The *ecopa* -Annual Workshop represents more than ever the DISCUSSION FORUM of all the four stakeholder parties for alternative methods development in Europe by now. Results and details of the *ecopa* Workshop of December will be given with the "messenger" in Qu. 1/2006. For those participating resp. interested, please find photos of the *ecopa* Annual Workshop here. The detailed meeting report will follow beginning of 2006: for those interested in new technologies such as biotech and nanotech, in the regulatory and alternative method testing in these areas this will certainly be a major infobox. An update of the *ecopa* status and activities, you will allways find in the NEWS section on the *ecopa* website. A time schedule for the CONAM/ecopa activities you will find here.
PDF: Time Line of CONAM/*ecopa* activites (56 kb)

During our Annual Workshop, major decisions were taken:
for those leaving our *ecopa* Board after a very successful working period (i. e. Coenraad Hendriksen, Arthur van Iersel, Karin Gabrielson - THANKS A LOT!), new members were elected, i.e.:
- Odile de Silva (L'Oréal, F)
- Roman Kolar (Akademie für Tierschutz, DE)
- Jan van der Valk (NCA, NL)
Let's welcome our new Boardmembers, and wish them all success and a lot of support in their new function.

Even more important, two new National Consensus Platform members i. e. Denmark and Hungary (Dacopa, Hucopa) and one new associated member, Ireland, were confirmed by the Annual Assembly: CONGRATULATIONS! Also, a publication procedure for the Board and the Working Groups was discussed and agreed to:
PDF: Article 19. Int regulation (12 kb)

After the outcome of the REACH discussions in the Committees, European Parliament and Council at the end of this year, we will hold our EU Chemical Policy Workshop on REACH now FINALLY on February 1st, 2006 - you will find the draft program. 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"

Registration form for the event on our website for download. As a special, participants will receive a free copy of the "animal test calculator" prepared by our Chemical Policies Working Group (THANKS to Simon and Karsten!)

And as usual, there are updates in this newsletter 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. It particpates in Bio-Sim by now, as well.

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

FINALLY, after a very industrious and successful year for *ecopa* , let me wish you, an behalf of the Board a

Merry X-mas and a Happy New Year.

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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Issue # 05 (November 2005)

ecopa:
- General News
- Statement regarding SCALE
- Technical Info to use the Forum of *ecopa*
- 7th Framework Programme - 2nd Update

EU 6th Framework Programme Projects / *ecopa* Working Groups:
- CONAM / Platforms
- ReProTect
- PREDICTOMICS
- eSI
- Sens-it-iv
- BioSim
- Lintop

Other Projects / Calls:
- Nanotech EU-Consultation
- 2006 Animal Welfare Enhancement Awards

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General News

Recent News on REACH

After the committees have finalized their discussions and the two largest parties (i.e. the EVP and the SPE) had agreed on a common line, the European Parliament did their voting on Thursday, November 17th.

The MEPs voted 407 for and 155 against the legislation, with 41 abstentions.

The compromize is oriented along the former discussion lines and the ENV council covered several aspects and it took place on November 28th.

The feeling is now that REACH could be in force by 2007, and fully operational by 2018(!). Guido Sacconi, lead rapporteur: "Not every one will laud this agreement, but we have a functioning minimum of REACH for all stakeholders."

See us at the *ecopa* REACH impact workshop on Febr. 1st, 2006, Brussels, Sheraton Airport!

ecopa has developed an impact software that will be distributed to all participants at the

workshop for free. This software will allow anybody to calculate the impact REACH will have on chemical testing requirements and on resulting animal numbers. All scenarios current and existing in future, can be modeled with it - it will be also downloadable later on from our website - it will give you the final "TOTAL" based on your individual input or REACH input. We will demonstrate the most recent outcome and impact of REACH at the workshop - here you have a preview of the face page.
PDF: Preview-image of the calculator (120 kb)

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:

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

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).

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 25.000 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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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.

NOTICE:
To avoid misunderstandings and because of inquiries at the ecopaAnnual 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. 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 within the next days. The name of the new association will be DACOPA - the Danish Ministery of Justice to be implementing it. CONGRATULATIONS!

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
2. Annual meeting

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.

UK Platfrom (The Boyd Group)

UK: BOYD GROUP ACTIVITY REPORT FOR *ecopa* , 2005

About 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.

Activities since the last *ecopa* workshop

1.Project and report on classifying the severity of animal procedures

Working in association with the RSPCA, the Boyd Group completed a project to examine current practice in the assessment of laboratory animal suffering and, in particular, the role and value of schemes for classifying the severity of animal procedures. Three focus groups were organised to explore these areas, involving:
- laboratory animal veterinary surgeons and animal care and welfare officers;
- representatives of animal welfare and anti-vivisection organisations; and
- researchers from a range of different establishments (all holders of project and/or personal licences under the UK Animals (Scientific Procedures) Act 1986).

The resulting report Boyd Group/RSPCA (2004). Categorising the severity of scientific procedures on animals: summary and reports from three round-table discussions. RSPCA Research Animals Department. http://www.boyd-group.demon.co.uk was widely disseminated late in 2004. It illustrates a remarkable convergence of opinion on the key issues and possible ways forward. The results have informed the discussions of a Working Group on Suffering and Severity, set up in 2005 by the UK government's statutory advisory committee on the use of animals in scientific procedures, the Animal Procedures Committee (APC).

Further, as a result of involvement in the focus group discussions, the UK Laboratory Animal Science Association (LASA), in association with the APC and the Boyd Group, has recently completed a pilot study of the feasibility of retrospectively reporting and publishing data on the severity of suffering actually experienced by animals in scientific procedures, for public information. The report of this study will be published soon, via the APC's web-site (http://www.apc.gov.uk).

2.Project concerning the education of new biomedical researchers

The Boyd Group is now pursuing a project aimed at enhancing new biomedical researchers' understanding and acceptance of the key principles outlined in the Boyd Group/RSPCA report, by:
1. reviewing current UK provision of training and other support for the development of new biomedical researchers - understanding of laboratory animal welfare science and ethics, and

their influences on scientific results;
2. considering and recommending practical steps to help fill gaps and meet researchers' needs;
3. collating and, if necessary, preparing resources to guide and support biomedical researchers' personal development, training and engagement in this area.

3.Targets

In the last two months, dialogue has been initiated within the Boyd Group regarding the possibility of setting national 'targets' for the elimination or reduction of certain current uses of laboratory animals (and better application of the Three Rs). This will involve participants from 'all four parties' (including both anti-vivisectionists and researchers who use animals).

Boyd Group/RSPCA (2004). Categorising the severity of scientific procedures on animals: summary
and reports from three round-table discussions. RSPCA Research Animals Department. http://www.boyd-group.demon.co.uk.

Polish Platform (polcopa)

Yearly Report Polcopa 2005

The Polcopa Founding Committee was finally established. The members who agreed to contribute the development of the platform are:

ACADEMIA:
Prof. B. Pastuszewska; Kielanowski Institute of Physiology and Animal Nutrition, Polish Academy of Sciences
Dr M. Stepnik; The National Centre for Alternative Methods in Toxicity Assessment (NCAM)

INDUSTRY:
Dr R. Debowska; Dr Irena Eris Cosmetic Laboratories
Dr M. Jozefowicz; Procter & Gamble

ANIMAL WELFARE:
1. W. Muza; Polish Society for Protection of Animals
2. P. Grzybowski; GAJA Association for Animal Protection

GOVERNMENT:
Dr D. Sladowski; Warsaw Medical University; The National Ethics Committee on Animal Experimentation

Draft of the Polcopa Statute was prepared by NCAM and sent out to the Founding Committee members for consultation. The Statute was prepared according to the Polish Act on Associations (1989) and assumes Polcopa to be a non-profit organization. After reaching a consensus the Statute will be submitted to the
National Court Register.

The main aims of the Association are the following:
Organizing and supporting any activities aiming at development and promotion of scientific research in the field of alternative methods in toxicity testing on animals; gathering people working in this field; dissemination of the scientific achievements to different target groups; Representing the Polish Association on national and international level. The Association will realize its aims through: Organizing scientific meetings, seminars, training courses, conferences, public lectures etc. Cooperation with National and Local Ethics
Committees on Animal Experimentation, the Ministry of Health, the Ministry of Education and Science, as well as other departments, universities, institutions in Poland and outside, Cooperation with related associations in Poland and outside, Publishing activity, giving an opinion on current status and needs in the field of alternatives in Poland, Scientific advising and consultations concerning animal experimentation.

NCAM prepared a draft of Polcopa questionnaire on alternative methods available in Poland and sent it out to the Founding Committee members for consultation. After reaching a consensus the questionnaire will be sent out to identified target institutions.

NCAM created a draft Polcopa web site (www.imp.lodz.pl/polcopa) in polish version. This site will be continuously updated as well as transformed into English version.

Dissemination activity of Polcopa members included the following presentations/lectures and posters:

1. "Cosmeticus - meeting for cosmetic industry and scientists", 14.07.2005, Krakow, Poland.
Presentation: "In vitro and in vivo tests in polish cosmetic industry" by Bazela K.
Organized by The Centre of Innovation, Technology, Transfer and University Development, Jagiellonian University.

2. "Concepts of Animal Welfare" 15.X.2005, Bydgoszcz, Poland.
Presentation: "In vitro tests in cosmetology - alternative for animal research" by Bazela K. and Solyga A.

3. "Synergistic effect of three active cosmetic ingredients on human skin cell cultures" by Debowska R., Bazela K., Rogiewicz K., Eris I.
European Academy of Dermatology and Venerology, October, London, 2005.

4. Course on "New legal realities in the field of cosmetics", 26-28.01.2005, Warsaw.
Lecture: "Toxicity Assessment using Alternative Methods" by Stepnik M.
Organized by International Research Institute, Warsaw.

5. Course for physicians specializing in occupational medicine, 26.09.2005, Lodz, Poland.
Lecture: "Alternative Methods in Toxicology" by Stepnik M. Organized by Nofer Institute of Occupational Medicine, Lodz, Poland.

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)

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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!

Supervising Board Teleconference covering the next interim report, is scheduled for midst of January 2006

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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ecopa Science Initiative

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.

Recent News

The next eSI Workshop will be held in 2006, most likely end of September, again, at Purblo Acantilado near Alicante. Topic currently being discussed.

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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 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 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).

Recent News

CONAM / ecopahas 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.

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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.

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.

Flavia Zucco has been invited, as member of the *ecopa* board, to be a member of the Scientific Advisory Board (SAB) of this project and has attended the first SAB meeting, during the BioSim Conference held in Mallorca on 5-8 October 2005.

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.

F. Zucco will help the project to reach some of its 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

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Lintop

ecopa - Representative in Lintop is Horst Spielmann.
PDF: Lintop Summary (22 kb)

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Other Projects / Calls

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Nanotech EU-Consultation

The European Commissions had launched a public consultation on risk assessment methods for nanotechnologies. The aim was 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 were are asked to respond online by December 16th.

Opinion and consultation:
http://europa.eu.int/comm/health/ph_risk/committees/04_scenihr/scenihr_cons_01_en.htm

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

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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