

Dear ecopa-messenger subscribers,

This is the second "ecopa messenger" edition in 2005. It summarizes the activities of ecopa that already have been performed by ecopa in the first half of 2005 or that will be taking place in 2005 and beyond.

Also, the reports on some of the major past events are included, such as, an [abstract report on the Consensus Workshop in Slovenia](#), [the summary report on the ecopa Annual Workshop at the end of November 2004](#), [the first ecopa Board meeting of this year, resp. the CONAM Review Board meeting at the same time, on March 17th, 2005 in The Hague, Netherlands](#).

Details of the ecopa-activities and plans can be derived from both these last mentioned reports. Also, there are updates on the 6th FP projects that ecopa is participating in, such as ReProTect or PREDICTOMICS. There is a new project on the horizon: besides VIMPACT, there are more details to Sens-it-iv.

Any proposal or recommendation regarding style, content or distribution of the newsletter is highly welcome and appreciated (bgarthhoff@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 # 04 (July 2005)

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General News

Recent News on REACH

whereas activities around SCALE have calmed down at the EU level somewhat, also due to the change in Commissioners, activities around REACH are picking up again. In respect to animal testing to be envisaged, the ecopa Annual workshop with its discussions on SCALE and the sign-in statement apparently had impact.

Following a REACH workshop midst of May, held in Luxembourg, the free Parliamentarian Rapporteurs have confirmed their intention to follow the timetable leadin to a first reading of the legislation by autumn this year.

The rapporteurs (Guido Sacconi, of the Environment Committee, Lena Ek from the Industry Committee and Hartmut Nassauer from the Internal Market Committee) presented the main elements of their reports, with particular emphasis on improving workability and/or reducing the burden on SMEs, as well as optimizing the balance between costs and benefits of the REACH proposal.

At the same time, the Luxembourg Presidency said it was of the opinion that "sufficient information is now available from impact assessments to allow the further consideration of complementary proposals to the Commission's" text.

The REACH workshop ran over two days and focused on the outcome of impact assessment work and the workability of key processes in the legislation. It was attended by key members of the Commission, Parliament, NGO's and trade unions, but requests from overseas governments to participate were rejected.

Chemical industry representative bodies have confirmed that the US and South African governments had asked to have some involvement in the two-day meeting, but the request was denied.

It is understood that requests from ten countries to attend were turned down.

The European Parliament's Environment Committee is now considering 1,183 amendments to the European Commission's proposed rules for the Registration, Evaluation, Authorisation and Restrictions of Chemicals.

The Committee has held several discussions this year on a report on REACH compiled by MEP Guido Sacconi, although it has not yet adopted any amendments. The Committee intends to hold a vote in September, prior to a full Parliamentary vote in October. Mr. Sacconi and MEPs from other political groups are now working on compromise amendments to simplify the vote. While MEPs agree with REACH's aim to generate risk assessment data for chemicals, many recognise the considerable cost impact that the new complex regulations may have on regulators and industry.

REACH key dates:

July 12, 2005: Internal Market Committee

August 30, 2005: Industry Committee

September 15, 2005: Environment Committee

October 27, 2005: Parliament Plenary

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, Authorisation and Restrictions of Chemicals, which includes substances such as agrochemical ntermediates and co-formulants.

News on Dates

- Informative meeting on July 08, 2005, Brussels with EU Commission-representatives on further 6th FP calls regarding alternative methods. This call (Intelligent testing strategy for chemicals) is most likely to be scheduled for November.

 [PDF: 6th Framework Programme for RTD \(108 kb\)](#)

Registration under: <http://www.cordis.lu/sustdev/environment/ev20050609.htm>

- ReProTect - Board Meeting on July 14, 2005, Tübingen, Germany following the Annual Research Area Meeting which took place in Ispra, Italy, May 31 and June 01, 2005. ReProTect is one of the major 6th FP projects supported and directed in the Board by

ecopa representatives.

Other News

There is a new quarterly newsletter "Forward Focus" out regarding alternative testing supplied by P&G. It will be distributed via email and posted online at:

http://www.pg.com/science/animal_alt.jhtml.

Also, P&G will be presenting Awards for European Welfare and Alternatives over 25000 Euro each. Applications are due by August 17, 2005 and application procedures are provided at:

http://www.pg.com/science/animal_alt.jhtml.

A Ukranian translation of the alternative website InterNICHE, the International Network for Humane Education, has been launched on June 16: <http://www.interniche.org/ua>

 [PDF: 2005 Procter and Gamble European Welfare and Alternatives Awards \(92 kb\)](#)

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Statement regarding SCALE

During the ecopa Annual Workshop, 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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First update on the 7th Framework Programme

Status June 2005

Overview on FP7 and Technology Platforms (first rough funding estimates)
Cooperation Collaborative research

1. Health (~8.4 bn EUR)

2. Food, Agriculture and Biotechnology (~2.5 bn EUR)
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

 [PDF: First update on 7th Framework Programme \(60 kb\)](#)

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eSI - ecopaScience Initiative Workshop

This initiative of ecopa was started to involve more young scientists, and get other research area scientists interested in the development of alternatives. The first eSI-Workshop in Pueblo Acantilado near Alicante/Spain was held in 2004 ([eSI Workshop](#)), and because of the success, a follow up in 2005 or 2006 is currently being discussed.

Report on the ecopa Annual Workshop 2004, workshop 2005

The Report of the ecopa Annual Workshop of November 26 - 28, 2004 is giving the details of presentations given on that occasion. The next ecopa Annual Workshop will take place on November 26-27, 2005 and there will be a preceding workshop regarding chemical testing in the context of the then final REACH requirements.

 [PDF: Minutes of the 5th ecopa Workshop \(330 kb\)](#)

Workshop "consensus platforms in practice", Ljubljana June 9 - 12, 2005

This workshop took place in Slovenia and addressed the actual work in consensus platforms. Representatives of the different platforms (NCP - National Consensus Platforms) participated and discussed the context of cooperation, when coming from different stakeholder parties. The workshop is part of the ecopa CONAM Project, and was organized by the Ethical Working-Group.

Please find a first abstract report of the meeting under:

 [PDF: Ecopa Meeting Slovenia \(20 kb\)](#)

A few pictures of the workshop can be found under this link:

[Pictures of the workshop](#)

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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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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

Minutes of the 2nd ecopa/CONAM (review 1) Board Meeting
ZonMW, Den Haag, The Netherlands, March 17, 2005

 [PDF: Minutes of the 2nd ecopa/CONAM \(review 1\) Board Meeting \(90 kb\)](#)

Platforms

Spanish Platform ([REMA](#))

Activity Report

REMA, the Spanish national platform of ecopa was officially established in a Scientific Meeting held at the Spanish Ministry of Health (Madrid, Dec. 1, 1999), and organized by a promoting commission of alternative methods supported by Glaxo-Wellcome. The aim of the meeting was to establish the Spanish Network of Alternative Methods (REMA, Red Española de Métodos Alternativos). In the meeting, the goals of the Spanish platform were presented and more than 100 participants representing academia, industry, animal welfare and government manifested their interest for the initiative. The members of the first board were selected in order to create a national foundation or society for the development of the project.

REMA is a founding member of ecopa, an initiative that was first discussed during the World Congress on Alternatives held in Bolonia (1999).

Registration:

REMA was registered as an official society in the Spanish Register of Societies (Nov. 12, 2002; nº 169.901)

The members of board in 2004:

Argelia Castaño, President
M José Gómez-Lechón, Treasurer
Adela López de Cerain, Secretary
Nuria Basi
Jose Vicente Castell
Francisco Ferrándiz
Consol Fina

Eduardo de la Peña, Vicepresidente
Pilar Prieto
Guillermo Repetto
Eugenio Vilanova

Meetings organized by REMA in 2004:

- II National Meeting of REMA. "Genomic, proteomic and citomic: new tools for drug development", Madrid, March 1, 2004
- Board meeting: Madrid, July 1, 2004

Presentation/participations in scientific and other meetings in 2004:

- Jose Vicente Castell and Eugenio Vilanova: 5th Annual Ecopa Workshop. Brussels, Nov. 26-28, 2004.
- M^a José Gómez-Lechón: two conferences about alternative methods in October 2004. Argelia Castaño: "Alternative methods in research". In: "Course about research animals protection" organized by the "Ministerio de Agricultura, Pesca y Alimentación" for animal facilities responsables. San Fernando de Henares (Madrid), Nov. 10-11, 2004.

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

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

Serum Free Cell Culture Media

One of the "zet" main activities during the last months was to finish the updated product guide about serum free cell culture media. As zet wishes to present a much broader range of serum free speciality media/supplements available by an increasing number of companies exists, but the gathering of product information is time consuming and often difficult. Furthermore, information provided by the industry naturally focuses on their own array of products neglecting competitor developments and are therefore often limited, sometimes outdated.

In the "zet" product guide, information is collected about more than 420 products from 62 companies. The product guide can be downloaded free of charge from the webpage www.zet.or.at/publikationen/Studien/fcs_update_1_2004.htm

Potential prevention on the use of apes for animal experiments in Austria

During the last year "zet" was involved in the discussion about prevention of the use of apes for animal experiments. On December 10th, 2004, all 4 political parties represented in the Austrian parliament supported an application which amongst others called on the Federal Minister for Education, Science and Culture, Mrs. Elisabeth Gehrler, to devise a proposal for modifications of the Austrian law concerning animal experiments, so that animal experiments using apes will be prohibited. Some days ago, this requested proposal was presented and sent to different organisations for legal advice.

German Platform ([s e t](#))

Activity Report

"set" concentrated its main activities in 2004 again on supporting various research projects, such as:

- Validation of an in vitro-test to define the toxicity of Botulinum-toxin A.
- Programme to reduce animal tests in the field of pain, and it's lessening.
- Participation in a research program of the local state of Rhineland-Palatinate to develop a larynx model for laser surgical operation.
- Study about the dog as second species for the safety testing schedule required for the registration of crop and plant protection products.
- Continuation of the project initiated by set formerly, to review the demands of the European monograph in the context of animal testing for quality control of drugs.
- Financial support for the ecopa eSi-Workshop of „Reaching the Young Scientist“ in Alicante.

All together the financial support amounted to more than 200.000,00 €.

"set" again sponsored the Toximed Centrum in Santiago de Cuba for its workshop "ALTERNATIVAS 2004" and the 12th European Congress for Alternative Methods in Linz Austria, 15. - 17. October 2004 as well as the Journal for Alternative Methods „ALTEX“.

Together with the Spanish platform REMA and the industrial platform organisation IVTIP, "set" submitted an application for a project in the EU 6th Framework Programme (calles VIMPACT), in order to accomplish a study regarding problems, effectiveness, implementation and putting into practice projects on alternative methods in the 5th EU Framework Programme, which comprised a total funding volume of 10 Mio. €.

Finally, "set" is sponsoring the 5th World Congress for Alternative Methods from 21 – 25 August 2005 in Berlin by an allocation of 20.000 € for at least 20 scholarships and 10.000 € for the session 7.3 "Innovative Approaches for Alternative Methods Development" of the congress.

Further, a main activity was also the enforcement of PR work on "set" and the relaunch of the "set" Website.

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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 José 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 3rd ReProTect Supervising Board Meeting
January 24, 2005, V.U.B., Brussels

 [PDF: Minutes of the 3rd ReProTect Supervising Board Meeting \(64 kb\)](#)
At present not available for the public!

Next Date: Supervising Board Meeting, Tübingen, Germany, July 14, 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 €. 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](#)

A further meeting was held near Innsbruck, Austria, April 12-14, 2005.

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The ecopaScienceInitiative is a project ecopa had initiated at its last Annual Workshop in November 2003 in Brussels ([Minutes of the Fourth ecopa Workshop](#)). The ecopa Management Board members had campaigned for it on different occasions and had also talks with representatives of the Cabinet of DG RTD of the EU Commission in that respect.

With substantial support of s e t , the German National Platform, Procter and Gamble, as well as Bayer CropScience, the Department of Toxicology at the VUB, the Dept. de Bioquimica at the Hospital Universitario La Fe of Valencia, this essential activity could be performed, and the workshop could be organized near Alicante, Spain (<http://www.uv.es/~jcastell/indexESI.htm>)

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

[Pictures of the eSi-workshop](#)

[Quotes of eSi participants & speakers](#)

[eSi Report \(PDF-File\)](#)

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EU 6th Framework Programme Projects / ecopa Working Groups

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This 6th Framework Programme is innovative primarily by the coordinated and extensive characterisation of the impact of compounds on cell-cell interactions for identification of the key mechanisms of sensitisation. Consistency with existing and ongoing projects, and optimal exploitation of these achievements is ensured by the involvement of ECVAM, COLIPA, ecopa, IVTIP and OECD in various levels of the project. ecopa is involved as a partner.

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 haptens-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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This envisaged project within the 6th Framework Programme is supported by the NCPs, REMA, s e t and by IVTIP. The need for Alternatives to Animal Testing under the 3-Rs concept (Replacement, Refinement, and Reduction) has been a main objective in the Programme financed by the EC. It is generally accepted that projects financed by the EC fulfill their scientific objectives, but it has not been properly examined to what extent the granted projects have reached in their socio-economic impact. This issue has been clearly identified as a priority in the FP6 November 2004 call. This proposal is justified by the necessity of improving research efficiency and its dissemination or transfer for higher socio-economical impacts. Annually, hundreds of thousands of animals are used and there is consensus among scientists, industry and policy makers, that properly validated alternatives methods are urgently needed. With this reason the European Commission installed ECVAM, the European Center for the Validation of Alternative Methods. With a few exceptions, alternative tests developed under the 3rd, 4th or 5th Framework Programmes (FPs) have not been submitted to an ECVAM consideration for pre-validation and/or validation. The gap between academic model systems and use in an industrial setting needs to be bridged. This gap could be filled by an in-depth socio-economic review of the projects results by independent experts, who may indicate possibilities for applications. This would help the EU to get the most out of its investment in research, and lead to an advanced transfer of technology to application. It is therefore proposed that the five research projects funded by the European Commission under FP5 will be subjected to such an in-depth review focus on their social and economical impact and the possibilities for application of the results. The results will be described in a report, and for the most promising issues extracted from the projects an Action Plan will be designed and communication with stakeholders will be mediated.

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Other Projects / Calls

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Training Course on alternative (non-animal) test methods for the hazard identification of

chemicals – will take place at the Institute of Pharmacy in Berlin from 26/09/2005 to 28/09/2005.

For more information please visit: <http://userpage.fu-berlin.de/~invitrot/>.

{-disclaimer-}