

Dear ecopa messenger subscriber,

In terms of conferences on 3R-alternatives, the end of the year 2007 will still offer a lot of opportunities, having had the 6th World Congress in Japan only recently, in August 2007. Next to come is on Monday, Nov. 5, 2007, the annual meeting of the epaa-Partnership between the EU-Commission and the Industry, covering especially the regulatory aspect. With the invitation, there was also attached the [questionnaire for carcinoGENOMICS](#), developed by the ecopa-directed Work Package 11 of that EU 6th Framework Programme Project. Filling in also possible by our [online programme](#).

And also, of course, the annual ecopa workshop on November 24/25, 2007 at the Sheraton Brussels Airport: this time with new member platforms joining and the Board elections.

 [8th Annual ecopa Workshop - Draft Programme \(40 kb\)](#)

 [8th Annual ecopa Workshop - Registration Form \(36 kb\)](#)

As had already been mentioned in the last editorial and transpired from the diverse projects currently running and addressing alternatives, the issue of appropriate cell systems and potential for risk assessment procedures will be in the foreground of the scientific part of the ecopa workshop. "Potential improvement in the development of alternative methods: Needs in risk assessment of new technologies and their products vs use of alternatives."

With that topic, ecopa once again addresses areas which are of impact, but not appropriately covered up to now in the context of the alternative methods area. In that regard, [the new ecopa EU 7th FP-project START-UP](#) (support-action) Scientific and Technological issues in the 3Rs Alternatives Research in The process of drug development and Union Politics" will be a major topic that fits into that overall subject, and that ecopa is following with its member NCPs.


And, finally, there are project updates, as well as some [information on a new 7th FP-project](#), where ecopa is participating in the dissemination of the results.

Next newsletter will be the Xmas-edition covering the outcome of the Annual Meeting in November.

Any proposal or recommendation regarding style, content or distribution of the newsletter is highly welcome and appreciated (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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I.1. General News

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I.1.1. Recent News on REACH

Most of the facts and the implementation aspects of REACH are found in the 60-page-report "Impact of REACH", first edition of a new series of *ecopa*-publications (electronic version). A print-version is available on request. Copies on CD also available, contact the *ecopa* secretariate.



[Impact of REACH \(804 kb\)](#)

The REACH implementation is further progressing by the search for the first executive director of the European Chemicals Agency (ECHA) headquartered in Helsinki, started operating on June 1, 2007. The director is to be appointed with end of this year, with an initial 5-year term in office. During the early months, the new director and the other newly recruited staff (about 100 by the end of 2007, 450 by 2010) will be supported by 40 officials seconded from the Commission, mostly out of the JRC Ispra.

Meanwhile, REACH-implementation progresses on a somewhat slower pace. Maybe, the view of one German MEP, Alexander Graf Lambsdorff, uttered in April of this year (ICIS, April 8, 2007, p.5.) will hold true: "This may well lead to the newly created European Chemical Agency (ECA) being overwhelmed with applications to the point where it can't do its work properly. ...[The EU] was very ambitious in making demands of industry without taking into account whether there are enough toxicity experts and analysts in the marketplace to conduct the testing." In the meantime, governments are preparing, and making in their presentations and courses use of the *ecopa*/CONAM report "Impact of REACH", especially they use the *ecopa* Animal Test Calculator. Software for free download.



[ecopa REACH animal testing calculator \(572 kb\)](#)

The *ecopa* calculator and the number of animals used were part of the lecture of E. Annys from Fedichem during his talk at the VIB toxicogenomics Symposium in Brussels on October 26, 2007



[VIB toxicogenomics Symposium - Programme \(68 kb\)](#)

Also, during an officially obliged training course in Belgium on animal use (to be followed by research leaders and PhD students working with animals), *ecopa* and its work were also explained to the students.



www.epaa.eu.com

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I.1.2. European 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 7, 2005 – a follow-up on this approach "**Europe goes alternative**" will be held each year.

Events:

This year's conference focuses on regulatory acceptance:

Workshop on "Regulatory acceptance of 3 Rs methods and strategies"

November 5, 2007, Brussels, Belgium, European Commission/DG Enterprise and Industry

Further information on the website:



<http://ec.europa.eu/enterprise/epaa/conf.htm>

Progress report 2007 just published:

 <http://www.indepaa.org/EPAA/Pages/download?docid=4987>

For report 2006 see here:

 http://ec.europa.eu/enterprise/epaa/epaa_progress_report_2006.pdf

The EPAA has agreed for 21 activities to be carried out over the next 5 years. Current co-chairs are: Mme Lalis, Mr Charles LaRoche (DG ENT, Unilever). As co-chair representing industry in the EPAA, the *ecopa*-Board-member and treasurer Dr. Bernward Garthoff, DMV, was elected in September. Serving in his function during 2008 together with Dir. Georgette Lalis of DG ENT, representing the Commission in the partnership, the important phase of the REACH-implementation is addressed. Welcoming addresses given by Comm. Potocnik and a Bayer Board representative.

A mirror group of stakeholders including animal welfare bodies and patient groups had again input into the process in the recent Mirror Group Meeting on June 6, 2007. The minutes of this meeting are soon to be found on the EPAA website. *ecopa* is represented here by three of its members.

 <http://ec.europa.eu/enterprise/epaa/uc.htm>

For the 4th EPAA-newsletter, see the website:

 <http://ec.europa.eu/enterprise/epaa/news.htm>

I.2. Other News * top

I.2.1. Nanotech

Besides of the discussions on the [ecopa Annual Workshop 2005](#) on new technologies, several partners have worked and discussed on nanotechnology, e.g. [at the last eSI-workshop](#).

The US Environmental Protection Agency (EPA) and its Science Policy Council has issued a nanotechnology white paper. The paper is aimed at providing information on the science issues and needs associated with nanotechnology, and to communicate them to stakeholders and the public.

 <http://www.epa.gov/osa/nanotech.htm>

I.2.2. Review of Directive 86/609

On June 25, 2007, Green MEP Satu Hassi tabled an oral question for the Commission on the review of the Directive 86/609 on animal testing, asking about the timeline for the publication of the proposal and reasons for the delay:

Committee on Environment, Public Health and Food Safety oral question from Satu Hassi (Verts/ALE, FI) to the Commission:

 http://www.europarl.europa.eu/meetdocs/2004_2009/documents/cm/672/672183/672183en.pdf

II.1. EU 6th Framework Programme Projects / *ecopa* Working Groups * top



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II.1.1.1. Recent News on FP6 and FP7 projects

The last *ecopa* Board meeting was held on September 27, 2007 in Linz, Austria, before the 14th Congress on Alternatives to Animal Testing. Next Board meeting will be held in spring 2008.

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

- *SSA project ForInViTox* (Forum for researchers and regulators to meet manufacturers of toxicology test methods) - *ecopa* is represented by Dr. Odile De Silva.
- *BioSim* - Flavia Zucco represents *ecopa* in this EU Project.
- *CarcinoGENOMICS* - Bernward Garthoff is the *ecopa* representative in this IP FP6 project. *ecopa* has taken over the Work Package of dissemination of results of the consortium. [A questionnaire of the WP 11 regulatory group](#) can be found on the *carcinoGENOMICS* website for consultation and input.

Input is requested and welcome from representatives of regulators, authorities, agencies and especially from toxicologists in industry and academia.

- *ACute Tox* – Peter Maier is the representative in the Advisory Board.
- *Sens-it-iv* – Vera Rogiers (represented by the *ecopa* secretariate) 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.
- *CONAM* – The last CONAM and Board review meeting was held on March 6, 2007 in Paris. The CONAM-project has, thus, successfully been finalized by submitting the final report.

II.1.1.2. Platforms

II.1.1.2.1. Austrian Platform

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

- The Linz-congress has taken place on September 28-30, 2007, the “14th Congress on Alternatives to Animal Testing & 11th Annual Meeting of MEGAT - Middle European Society for Alternatives to Animal Testing”, Linz, Austria.

II.1.1.2.2. Belgian Platform

» [Foundation Prince Laurent](#)

II.1.1.2.3. Czech Platform

» [CZECOPA](#)

II.1.1.2.4. Danish Platform

» DACOPA

- DACOPA has decided to postpone the Opening Symposium initially scheduled for November 9, 2007. The new date will be sometime during 2008; exact date has not yet been decided upon.

II.1.1.2.5. Dutch Platform

» [NCA - The Netherlands Centre Alternatives to Animal User](#)

II.1.1.2.6. Finnish Platform

» [Fincopa](#)

- A short report of the meeting of Fincopa board (Helsinki, August 17, 2007).

The meeting was the first meeting of the board elected in the business meeting in May 2007. Professor Hanna Tähti stepped down as chairman (2003-2007) of Fincopa, and is now followed by Dr Eila Kaliste.

The new board is:

Dr. Eila Kaliste (President), Dr. Paula Vesa (Secretary), Dr. Marianna Norring (Treasurer), Prof. Kirsi Vähäkangas (Vice- President), Dr. Christina Björklund, Dr. Helinä Ylisirniö, Prof. Hanna Tähti (Past President) and Dr. Kimmo Louekari. The members represent the four parties as follows: research (2), administration (2), animal protection (2) and industry (2). In addition there are nominated vice members for each board member. The complete list can be found at the web page of Fincopa:



<http://www.uta.fi/jarjestot/fincopa/index-suomi.htm>

- The coming activities of Fincopa were discussed. Fincopa will organize in connection of the annual meeting on Spring 2008 a seminar. In this seminar, state of the development of alternative methods will be presented. The follow-up of the alternatives applied in REACH will be another important topic.
- The board discussed the strategy and coordination of the cowork in the development of alternative methods in Finland. The process should follow the proposals presented in the Memorandum of the working group of the Ministry of Agriculture and Forestry, published in 2006. One of the proposals was that “ A national Centre for Alternative Methods should be founded to promote, organizes and coordinate research, communication and education on alternative methods”.
- The contacts with Estonian colleagues and the possibility to organize the Finnish–Estonian cowork in *ecopa* were discussed.
- Prof. Kirsi Vähäkangas was elected to represent Fincopa at the *ecopa* meeting November 24/25, 2007.
- Five new members were elected.
- The next board meeting will be on Dec. 04, 2007.

II.1.1.2.7. Latest news on the creation of the French platform

- The set up of the French platform has been finalized. The official meeting is scheduled for November 16, 2007, Paris, France. Isabelle Fabre will present the French platform at the next *ecopa* meeting on November 24/25, 2007. Our chair Vera Rogiers will be present and introduce the work of *ecopa*.

In summary, Afssaps (Agence Française de Sécurité Sanitaire des Produits de Santé) will be the coordinator of this project and will be associated with Afsset (Agence Française de Sécurité Sanitaire de l'Environnement et du Travail) and Ineris (Institut National de l'Environnement industriel et des Risques) for the regulatory representation. The Ministry of Research will be hosting the plenary meeting which is to establish the structure of the platform and define the activities to follow.

- Two **animal welfare** organisations are already involved as partners, such as OPAL (Oeuvre pour les animaux de laboratoire) and LMDA (Ligue Française des Droits de l'Animal). At this time, an official procedure is ready to be sent out in order to involve private and public research institutions. The addressed partners from the **Public research are the following**; CNRS (Centre national de la Recherche Scientifique), INSERM (Institut National de la Santé et de la Recherche Médicale) and from **Industry** (official procedure); Cosmetic – FIP (Fédération des Industrie de la Parfumerie), Chemical – UIC (Union des Industries Chimiques), Drug – LEEM (Les Entreprises du Médicament), **SPTC** (Société de Pharmaco-toxicologie Cellulaire).

II.1.1.2.8. German Platform

» [Stiftung set](#)

- The Annual Report for 2006 has been approved by the council on June 28, 2007 and is to be found on the website.

 <http://www.tierversuche-ersatz.de/>

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

II.1.1.2.9. Hungarian Platform

- The new executive Board has been elected:
It consists of Lajos Balogh, chair, Eva Hercsuth, heading the Animal welfare platform, Prof Tibor Bartha, heading the Academy, Laszlo Pallos, Authority Zsuzsa Somfai, Industry.

II.1.1.2.10. Italian Platform

» [IPAM - Italian Platform on Alternative Methods](#)

-  [PDF: IPAM annual report 2006 \(5 kb\)](#)

II.1.1.2.11. Irish Platform

II.1.1.2.12. Norwegian Platform

» [Norwegian School of Veterinary Science](#)

- With the assistance of the Norwegian Ministries, a permanent, *ecopa*-style, National Consensus Platform in Norway was established. The official opening ceremony took place on October 10, 2007, in Oslo/Norway, at the Norwegian School of Veterinary Science. Our treasurer Bernward Garthoff was present and introduced the work and support of *ecopa*.

 <http://oslovet.veths.no/fag.aspx?fag=56>

Presentation by Dr. Bernward Garthoff on the occasion of norecopa-Opening Symposium:

 [PDF: Presentation by Dr. Bernward Garthoff \(1,8 MB\)](#)

II.1.1.2.13. Polish Platform

» [polcopa](#)

II.1.1.2.14. Spanish Platform

» [REMA – Red Española para el Desarrollo de Métodos Alternativos a la Experimentación Animal](#)

- The REMA activities can be found can at (Spanish version):

II.1.1.2.15. Swedish Platform

» [Stiftelsen Forskning utan djurförsök](#)

- Karin Gabrielson is replaced by [Cecilia Clemedson](#) due to her maternity leave, who is the official contact for Swecopa. [Staffan Jakobsson](#) will be the deputy chair of Swecopa until the next Annual General Meeting.
- **Government support for 3Rs research**

The Swedish Animal Welfare Agency was closed down in July of 2007, and it is still not known how the government funding for 3Rs research will be administrated in the future.

The next AGM initially foreseen for spring 2007 has been postponed.

- The official website is available:

 <http://www.swecopa.se>

II.1.1.2.16. Swiss Platform

» [3R Research Foundation Switzerland](#)

- Update on Activities:

Latest bulletin of May 2007 to be found here:

 <http://www.forschung3r.ch/en/publications/bu35.html>

Meeting to mark the 20th anniversary of the 3R Research Foundation and the 20th anniversary of the Swiss Laboratory Animal Science Association (May 2007).

This meeting was held on September 3-4, 2007 at the Zurich-Irchel University in Zurich. On both days more than 400 persons attended the conference, The focus on day 1 was on „Humane Endpoints“. 39 speakers from Germany, Netherlands and Switzerland presented their results and shared their experience with the audience in two parallel sessions and 4 workshops.

On day two, the focus was on the 3Rs in all his facets (see program). More than 260 persons attended the 3R sessions. 14 invited speakers showed how the 3Rs improve animal welfare, experimental design and results (see photos). The summaries of the papers given have been collated in a 70 page brochure.

 [PDF: 3R-Brochure \(1,8 MB\)](#)

 <http://www.forschung3r.ch/en/news/index.html>

On March 26, 2007 the Administrative Board approved the Annual Report for 2006 Direct link:

 <http://www.forschung3r.ch/en/information/jb06.html>

II.1.1.2.17. UK Platform

» [The Boyd Group](#), founding member of *ecopa*, decided to withdraw from the *ecopa*-umbrella-activity, effective November 2007.

- Further information and reports are available at the Group's web-site:
» <http://www.boyd-group.demon.co.uk>

Interested to form a new national platform in your country?

Please contact us (» [contact section](#)).

For an upfront info how to create a platform in your country, and which criteria to apply? See also the presentation of Jose Castell at the Stakeholder Workshop in Prague ECVAM/*ecopa* Stakeholder Workshop:

 [PDF: A guided tour to become full members/associate members in *ecopa* \(200 kb\)](#)

All the abstracts of the following projects are to be found on the forum of the *ecopa* website, see the comment under II.1.

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.

II.1.2.1. Recent News

The last Supervising Board Meeting was held on June 28/29, 2007 in Madrid, Spain

The Annual Research Area meeting and the Meeting of the Executive Committee will be held in Ispra, Italy Nov. 26/27, 2007. A brochure on the ongoing activities is available.



[PDF: ReProTect Brochure](#)



[PDF: Executive Summary \(224 kb\)](#)

Also, please find a respective flyer below, and the brochure with first results.



[PDF: ReProTect Flyer \(320 kb\)](#)

ecopa is involved in the Board and the results dissemination.

PREDICTOMICS www.predictomics.com

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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.

II.1.3.1. Recent News

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



[PDF: Publishable Executive Summary](#)

The consortium has launched a new website 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 5th meeting took place on April 18-19, 2007 in Dublin.

Websites: www.predictomics.com or www.predictomics.org



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



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



www.acutetox.org

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II.1.4.1. Recent News



[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 \(136 kb\)](#)

The first ACute Tox newsletter appeared in December 2006 with amongst others a summary of the

project results accomplished during the first project year. The last ACuteTox newsletter appeared in July 2007 and the next newsletter will be available and distributed by next month.

The main results achieved in 2006 are summarized in a press release which you can download from the website

 http://www.acutetox.org/docs/Press_release_ACuteTox_Augt_07_english.pdf

A mid-term report on the project has been submitted by end of September 2007.

 [PDF: ACuteTox Mid-term report \(92 kb\)](#)

You can subscribe to it by sending an email to ACuteTox@expertradet.se and in the mean while, it can be consulted on the website:

 <http://www.acutetox.org>



www.sens-it-iv.eu

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Sens-it-iv is an Integrated Project financially supported by a grant from the European Commission (LSHB-CT-2005-018681). 28 groups overall, of which 9 represent industry. 15 groups represent universities or research institutes, while 4 groups represent organizations.

II.1.5.1. Recent News

ecopa has taken over the responsibility "spreading the news/results" of this EU project, and released a brochure covering the activities on behalf of Sens-it-iv, and supported the website creation. The folder and poster can be downloaded on the website www.sens-it-iv.eu, section press material.

ecopa has taken over the responsibility "spreading the news/results" of this EU project and is, therefore, working in work package 9 called "Technology transfer and Dissemination". Technology transfer and dissemination of project results, including knowledge, will be a key activity throughout the term of the Sens-it-iv project. *ecopa* released a brochure covering the activities on behalf of Sens-it-iv, and supported the website creation.

The folder and poster can be downloaded on the website, section press material.

The eleventh newsletter will appear mid November. Subscription possibility on the website.

The General Assembly Sens-it-iv and Meeting of Sens-it-iv Management Team, Steering Committee took place on October 22-26, 2007 in Ispra, Italy.

 [PDF: Sens-it-iv - First publishable summary \(114 kb\)](#)



<http://www.biosim-network.net>

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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.

II.1.6.1. Recent News

The third scientific conference for the BioSim Network took place in Potsdam, Germany, from October 10-13, 2007.

The BioSim network of excellence, now in the third year of activity, has accomplished already many tasks. The first and most important one is that very coherent sub-networks assembled around specific topics. This is the case of diabetes, cancer and circadian rhythms, hypertension and cardiovascular diseases.

In those areas, mathematical simulation has been proven to be possible from gene expression to whole-body metabolism, covering, in between, also cell signalling, metabolic regulation and intracellular fluxes of molecules. The pathway of collaboration is still scattered, but the trials performed are very promising and, for some of them, is already possible to forecast clinical outcomes. The area of mental disorders and neuronal system is still in search of optimal interfaces among different possible collaborators, being competences still a bit far from each other: therapeutic effects of desynchronizing

brain simulation goes together with models for sleep-wake cycles or energy metabolism related to inclusion formation in neuronal disease. However a fruitful dialogue is started and integrated possible tasks are explored.

Some application has been shown concerning computer simulation in the design of clinical trials and in predicting human metabolic clearance, by incorporating population variability. More in general the aspect of the contribution of modelling and biosimulation to health care has been discussed and a relevant approach has been presented, consisting in the Innovative Medicine Initiative (IMI) which will be eventually approved by the end of the year (www.imi-europe.org). It is a joint initiative between the EU Commission and EFPIA, to launch a research project aimed at improving the drug efficacy and minimising the counter effects. An increased collaboration among industries and academia is at the basis of this effort.

Being biosimulation in the phase of blooming, the methodological aspects are of great interest: challenges of modelling cell synchronisation, the role of noise in cellular processes or mapping the sensitivity of regulatory networks are met with success, with the aim of applying them to other organisms or pathway in the search perhaps (again!) of the universal fundamental formula!

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

 <http://www.biosim-network.net>



Liintop

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II.1.7.1. Recent News

ecopa - Representative in Liintop is Horst Spielmann.

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

The Kick-off meeting of Liintop was organized on January 12-13, 2007 in Rome, Italy. The agenda of the last Management Team Meeting, held June 18, 2007 in Manchester, UK, can be found on the website.

 <http://www.liintop.cnr.it/img3/MTMeetingSchedule.doc>



CarcinoGENOMICS

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II.1.8.1. Recent News

The Kick-off meeting of CarcinoGENOMICS took place November 5-7, 2006 in Maastricht, the Netherlands.

 [PDF: CarcinoGENOMICS Press Release \(24 kb\)](#)

The third Board Meeting took place on Sept. 03, 2007 in Brussels. The 1st Consortium & General Assembly Meeting will be held on Nov. 6-8, 2007 in Valencia/Spain. A questionnaire of the WP 11 (the workpackage directed by *ecopa*) regulatory group is available on the carcinoGENOMICS website: www.carcinogenomics.eu for consultation and input. It will also be distributed at the forthcoming EPAA-meeting which is on regulatory aspects (Nov. 5, 2007/Brussels/Belgium).

 <http://www.carcinogenomics.eu/index.php?id=110>



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

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II.2.1. Sustainable Chemistry

The Technology Platform SusChem has been formed and finalized its Implementation Action Plan. The action plan can be downloaded from the SusChem website.

 <http://www.suschem.org/>

The 5th Stakeholder Meeting took place on March 8, 2007 at the Concert Noble in Brussels.

Presentations available on suschem website

 <http://www.suschem.org/content.php?pageId=3428>

The next event listed on the SusChem calendar is the 6th Stakeholder and brokerage event on **January 29-30, 2008** - in Berlin, Germany.

II.2.2. Preparation 7th Framework Programme Projects

The objective of a workshop "**EU funded research on alternatives to animal experimentation: stocktaking from FP6 and views for the future**" that took place on June 13-14, 2006 was to identify gaps in research in the area of development of alternatives to animal testing, to explore ways to close this gap, and to identify opportunities for strategic research activities to be formulated and implemented under FP7.

Additional info on this workshop with the official report and the new topics that were discussed for future projects can be found here:

 [PDF: Group A Report \(Contribution of QSAR/QSPR to alternatives\) \(960 kb\)](#)

 [PDF: Group B Report \(Nanotechnology and alternatives\) \(36 kb\)](#)

 [PDF: Group C Report \(Alternatives and Drug Discovery / Development\) \(88 kb\)](#)

Given *ecopa's* follow up-project START-UP (see topic II.2.4) the Group C report will be a basics for discussion.

II.2.3. Regulations of the 7th Framework Programme

Update 7th EU RTD- Framework Programme

Guidance on FP7 implementation

A number of guidance documents and preparatory work are carried out by the European Commission in view to install the basis of the FP7 implementation. The following documents are available for consultation on http://cordis.europa.eu/fp7/find-doc_en.html where they can also be downloaded:

- a standard Model Grant Agreement,
- a draft Guide for Beneficiaries,
- a draft Guide to Financial Issues,
- a draft Guide to IPR and
- a draft Checklist for the Consortium Agreement.

ecopa is interested to participate with partners in some of the calls dealing with alternative methods and being announced in the future, esp within the HEALTH resp. the ENVIRONMENT sectors of the 7th FRP.



START-UP

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ecopa submitted a proposal for a Support Action in the HEALTH-2007-1.3-2 call: Bottlenecks in reduction, refinement and replacement of animal testing in pharmaceutical discovery and development. The proposal is called "**Scientific and technological issues in 3Rs alternatives research in the process of drug development and Union politics**" with the acronym: **START-UP**. Several NCPs are collaborating in this project, if approved accordingly and negotiated with the Commission.

II.2.4. The Abstract of the proposal

The **START-UP** project is concerned with the identification and proposals to abolish bottlenecks in the 3Rs approach in pharmaceutical discovery and development. The goal of the project is the organisation of 3 **Workshops** in order to determine a) the state of the art of each of the 3Rs in the EU, b) to assess European strength and gaps in 3Rs and c) the identification of rate limiting steps on the political, scientific, technological level. As a result, a Consensus Paper containing the concepts and suggestions for a Roadmap for future research will be produced.

Stakeholders (among them European Pharmaceutical Industries (EPI)) have identified bottlenecks in drug development and in the integration of in vitro methods Early identification of wrong candidates for further development and avoiding efforts for under-performing candidates, are essential for the competitiveness of European Industry. Identification of bottlenecks in the implementation of reduction, refinement and replacement of animal experimentation in drug R&D, should assist in identifying the best

in vitro and in vivo systems, and to speed up the drug development process. Existing hurdles in the scientific, technological, political and environmental level (including regulatory), play a substantial role and are rate-limiting in developing new drugs, including biological entities (almost 50% of the currently developed products).

ecopa (the quadripartite umbrella NGO for alternatives) structures with its VUB partner this support action around 3 major workshops which will be preceded by 2 Expert Meetings redefining and prioritising current bottlenecks in 3Rs methodology; with EPI, drug discovery and development. Each phase has its own specific needs, and analysing the present limitations and gaps needs to be addressed, e.g., many cell systems do not yet have the required stability for genomics, proteomics or metabonomics analysis; many current in vitro cell systems lack crucial bioactivation capability. Consequently, the status of satisfactory "predictive" pharmacology and toxicology in vitro has not yet been reached.

In terms of politics and ethical concerns, considerable differences in regard to the use and development of transgenic animals, human tissues and stem cells create an atmosphere of insecurity for an effective academia and industry cooperation.

The final goal of this action is a Consensus Document that analyses present status.

Details of the project were presented by the Chair of *ecopa* on the occasion of the 11th Linz Alternative Congress, September 28-30, 2007.

 [PDF: Presentation by Prof. Vera Rogiers \(1,2 MB\)](#)

II.2.5. ESNATS

Project acronym: ESNATS

Project full title: Embryonic Stem cell-based Novel Alternative Testing Strategies

Grant agreement no.: FP7 - 201619

The aim of the ESNATS project is to develop a novel "all-in-one" toxicity test platform based on embryonic stem cells (ESCs), in particular human ESCs, to accelerate drug development, reduce R&D costs and propose a powerful alternative to animal tests in the spirit of the "Three R principle". ESNATS objectives will be achieved in a 5 year multi-disciplinary collaboration of leading European researchers in alternative testing, toxicology, ESC research, genomics, modelling, and automation. The consortium will also include representatives from regulatory bodies, the pharmaceutical industry and ethical advisors to provide guidance to ensure rapid applicability of the developed test systems.

ecopa has taken over some tasks in disseminating results of this project.

Miscellaneous

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III.1.1. *ecopa* events

III.1.1.1. 8th Annual *ecopa* Workshop

The next, 8th Annual *ecopa* Workshop is to take place on November 24-25, 2007 in Brussels. It will feature the topic "Potential improvement in the development of alternative methods: Needs in risk assessment of new technologies and their products vs use of alternatives".

 [8th Annual *ecopa* Workshop - Draft Programme \(40 kb\)](#)

 [8th Annual *ecopa* Workshop - Registration Form \(36 kb\)](#)

The future *ecopa* Annual Meetings will be:

9th: November 29-30, 2008

10th: November 28-29, 2009

III.1.1.2. *ecopa* Board meeting

 [PDF: Minutes of the *ecopa* Board Meeting: September 27, 2007, Linz, Austria \(32 kb\)](#)

The next *ecopa* Board meetings:

March 4, 2008

September 23, 2008

March 3, 2009

September 16, 2009

III.1.1.3. eSI: *ecopa* Science initiative

The eSI-Conference under the general heading: "Reaching the young scientist" is 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.

The full report, presentations, and the final program are listed [on the *ecopa* website in the archive section](#).

The next workshop is to take place in September 25-27, 2008 in Pueblo Acantilado; Alicante, Spain. It will focus on "Scientific activities regarding 3 Rs in the pharmaceutical and cosmetic arena: current and in future".

III.1.2. other events

III.1.2.1. In vitro Molecular Imaging: From Fluorescent Probes to Novel Techniques to Cellular Imaging

November 27-28, 2007, San Diego, CA, USA.

» <http://www.healthtech.com/conference-info.asp>

III.1.2.2. A first press conference if IMI, the "Innovative Medicine Initiative"

of the Pharmaceutical Industry and the Commission will most likely take place on December 13, 2007 in Brussels / Belgium (attending: Commissioner Potocnik, DG RES; President of EU Parliament Socrates; EFPIA President Higgins, Bayer AG)

Given the *ecopa*-interest, see also BioSim II.1.6.1 !

III.1.2.3. EUROTOX 2008

to be held in Rhodes, Greece from October 5-8, 2008. The theme of the Congress is "FROM TOXINS TO OMICS : HEALTH, SAFETY AND WELL-BEING". Its scientific programme comprises symposia and workshops accordingly whereas distinguished and renowned speakers will address the participants, presenting the current and latest scientific innovations, discoveries and practices on important subjects in the multidisciplinary field of Toxicology.

For more information visit:

» <http://www.eurotox2008.org/>

III.1.2.4. IN VITRO MODELS: NEW ALTERNATIVES, CURRENT STATUS AND REGULATORY REQUIREMENTS/EXPECTATIONS

to be held in the Sir James Black Conference Centre at AstraZeneca, Alderley Park, Cheshire on Tuesday, November 20, 2007. Registration forms to be sent to Dr James Sidaway (contact details on the form) by 31st October.

For more information:

» <http://www.ivts.org.uk/>

III.2. Awards and Publications

III.2.1. Announcement of the Doerenkamp-Zbinden-Prize 2008

The Doerenkamp-Zbinden Foundation for Animal-Free Research will again award a prize for outstanding achievements in scientific animal protection in 2008. Suggestions for the prize may be made by members of the Foundation Board or the Scientific Advisory Committee of the Doerenkamp-Zbinden Foundation as well as by recognized institutions of science and animal protection (e.g. universities, scientific societies, private research institutions, interregional animal protection organisations). Direct applications for the prize are not possible. Suggestions may be made by December 15, 2007.

If no convincing suggestions for a laureate are made to the Foundation Board, the prize will not be awarded in 2008. According to the deed of the foundation scientific methods which can replace or reduce animal experiments that cause pain and suffering, especially to non-human primates, dogs, rabbits and cats as well as pigs, horses and ruminants are worth funding. Work in basic research will be considered preferentially according to the new deed of the foundation.

The prize is endowed with 25 000 CHF and can be shared.

For more info see website:

» <http://www.doerenkamp.ch/en/default.html?id=64>

III.2.2. Dieter Luetticken Award

Winner Dieter Lütticken Award 2007

The annual Dieter Lütticken Award 2007, has been granted to Dr Mark Stevens from the Institute of Animal Health, United Kingdom for his commitment to advancing the 3R concept – reducing, refining or replacing the use of animals in research. The Dieter Lütticken Award aims to encourage research into the use of in-vitro models, which replace animal testing for product licensing purposes, as well as studies avoiding the use of animals in efficacy, safety and quality testing of biological and pharmaceutical products for animals. With a prize fund of 20,000 euros, the award is sponsored by animal health company Intervet and is intended to be presented to Dr Stevens by Dr Ellen de Brabander, Vice President Research and Development, Intervet at a special ceremony during the 6th World Congress on Alternatives in August in Tokyo, Japan. Dr Stevens' laboratory has developed several animal models to study the pathogenesis of enteric bacterial infections of livestock and uses novel genetic methods to dissect the molecular basis of bacterial virulence. The panel of expert judges characterized Dr Stevens' work as being a coherent and integrative approach to both applied and fundamental research that has significantly advanced the 3Rs. Particularly relevant in 'Refinement', was the work conducted in collaboration with other high level research groups on in-vitro organ culture models to quantify bacterial adherence and tissue tropism ex vivo, an original study at the leading edge of veterinary science.

Intervet actively screens at country level for suitable applications. However, Intervet welcomes submissions for the Dieter Lütticken Award from all scientists and life-science research institutions, excluding commercial organizations.

Announcement of the Intervet's award 2008

Intervet offers the Dieter Lütticken award to promote scientists or life science research institutions working in research areas that serve the 3R-concept i.e. reducing, refining or replacing the use of animals in testing for development and production of veterinary medicines. The total funding for the award is 20,000 Euro.

Application deadline is November 15, 2007. See website www.intervet.com

III.2.3. EPAA Newsletter, October 2007

The 4th edition of the EPAA-newsletter is available now.

» <http://ec.europa.eu/enterprise/epaa/news.htm>

III.2.4. New ECVAM Workshop Report no. 60 - now available online

ECVAM wishes to inform, that the new ECVAM Workshop Report no. 60 "Chemical Respiratory Allergy: Opportunities for Hazard Identification and Characterisation" is now online.

The Workshop Report can be downloaded from [here](#) or from the [ECVAM Website](#). Please select inside the section "Publications / Workshop Reports".

III.2.5. Biographics Laboratory 3R-newsletter (fall 2007)

The VirtualToxLab has been launched on the internet. It claims to estimate the toxic potential of drugs and environmental chemicals towards a total of currently nine receptor models completely in silico.

<http://www.biograf.ch/downloads/newsletter.pdf>

III.2.6. DG SANCO Newsletter

The second issue of the newsletter of DG SANCO concerning the activities of the Commission Scientific Committees SCHER (Scientific Committee on Health and Environmental Risks), SCCP (Scientific Committee on Consumer Products) and SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) has been published. This Newsletter is also available on DG SANCO website.

» SANCO-c7-newsletter@ec.europa.eu

III.3. Calls

III.3.1. CEFIC LRI - Call for project ideas in the area of the 3Rs

CEFIC has established an Animal Alternatives Issue Management Team (AIMT) to provide the European Chemical Industry with a credible and coherent platform for addressing issues relating to the refinement, reduction and replacement of animals in toxicity testing (3Rs).

AIMT also coordinates CEFIC's input into the European Partnership for Alternative Approaches in Animal Testing (EPAA) where industry is cooperating with the European Commission together with six other industry sectors.

AIMT works to identify and prioritize research needs resulting from current and future requirements in relation to the 3Rs as well as to develop and implement research projects within CEFIC's Long-range Research Initiative (LRI).

After a high-yielding first round of collecting ideas in 2004/05, a number of projects have been implemented and are nearing completion.

For the next round, we would like to call upon your support and creativity to identify potential areas where there are research needs of specific interest to the chemical industry. You are requested to submit ideas for research projects or other activities that might be candidates for the AIMT research portfolio (both from toxicology and ecotoxicology, e.g. refinements to reduce the number of animals in certain tests, development or modification of in vitro methods, development and use of QSARs, reliability of risk assessment etc.).

All ideas received will be prioritized and the highest priorities translated into Request for Proposals (RfPs) to be published. From the applications received for these calls, projects will be selected for implementation.

DEADLINE: Friday, November 9, 2007.

Information:

» <http://www.cefic-lri.org/>

III.3.2. 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.

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 November 24, 2008.

Document Reference: OJ No S 46-047741 of 8.3.200 RCN: 25319

III.3.3. Registration of Experts for FP7

The Seventh Framework Programme was fully operational as of January 1, 2007 and will expire in 2013.

Registration of Experts for Research Activities

The call for experts for the seventh framework programme has been launched

The personal data collected in the context of the present call will be processed in accordance with the Regulation (EC) n° 45/2001 of the European Parliament and of the Council of December 18, 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies on the free movement of such data.

» <https://cordis.europa.eu/emmp7/index.cfm?fuseaction=wel.welcome>

III.3.4. The ECLAM ESLAV Foundation is now accepting applications for funding in 2007-2008

It is a charitable organisation that funds studies for the discovery, validation and implementation of refinement of the care and use of animals in research.

In particular the Foundation funds small studies, up to 20000 euros in the following areas:

- Refinement in experimental techniques, anaesthesia and analgesia to reduce pain and distress
- Objective measures of animal welfare.
- Studies to ensure scientific basis for housing and husbandry standards
- Validation of environmental enrichment to improve behavioural well being

The Foundation's website can be found at:

» <http://www.eclameslavfoundation.org>

with a grant application form at:

» <http://www.eclameslavfoundation.org/applications.htm>

A leaflet describing the Foundation is available at:

»

III.4 VARIA

III.4.1 Public Consultation on the Green Paper 'European Research Area: New Perspectives'

The European Commission invites citizens and stakeholders to participate in the debate on the European Research Area (ERA), in particular by putting forward their views in this public consultation. The consultation is based on the questions raised in the Green Paper 'The European Research Area: New Perspectives'.

The results of the debate will be used by the Commission to prepare initiatives that will be proposed in 2008.

More detailed information can be found on:

» http://ec.europa.eu/research/era/consultation-era_en.html

For more information and to participate in the consultation please visit the consultation web site.

» <http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=ERAGreenPaper>

III.4.2. The NC3Rs - Information Portal - Species selection

The British NC3Rs has an extensive Information Portal where to find a wide range of references and links for guidance on implementing the 3Rs.

A new section on [species selection](#) has recently been added. Where animal use is necessary in research or testing, the choice of species (and breed/strain) should always be carefully considered and justified. This page sets out some of the factors to consider, particularly in relation to the 3Rs.